UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

MARY MADISON,	)	
	)	
Plaintiff,	)	No. 23-cv-16476
v.	)	
	)	Hon. Manish S. Shah
CREATIVE WERKS LLC,	)	
and STEVE SCHROEDER, Individually	)	
	)	
Defendants.	)	
	)	

Exhibit 1

IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF ILLINOIS

EASTERN DIVISION

MARY MADISON,

Plaintiff,

vs. Case No. 23-cv-16476

CREATIVE WERKS LLC, and

STEVE SCHROEDER,

Individually,

Defendants.

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VIDEO DEPOSITION OF

MARY MADISON

March 24, 2025

8:59 AM Central

Dickinson & Wright

55 West Monroe, Suite 1200,

Chicago, Illinois

Stenographically Reported By:

Deanna Amore - CRR, RPR, CSR - 084-003999
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APPEARANCES OF COUNSEL

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On Behalf of the Defendants, CREATIVE WERKS LLC, and STEVE SCHROEDER, Individually:

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ALSO PRESENT:

Scott Ziarko, Videographer
John Schroeder, Creative Werks
General Counsel & Senior Manager of Plant Operational System
Gretchen LeMay, Creative Werks, Head of People

Job Number: 7262234

* * * * *

puzzle is correct. This -- I mean, so I'm going to say limited to just the first blush, yes, this is what I drafted if this is exactly what belongs with this.

Q. Okay. So with respect to this document, then, you are the author of this document -- correct? -- as far as you know?

A. Yes, sir.

Q. And did anyone else assist you with the drafting of this document?

A. No, sir.

Q. Who was your supervisor when you worked at Creative Werks?

A. Erich Zicher.

Q. Eric Zicher?

A. Zicher.

Q. Z-i-c-h-e-r?

A. That's how he spells it.

Q. And do you know who his supervisor is or was when you were working there?

A. Not offhand.

Q. Do you recall Ronald Sammeth?

A. I think I've heard that name before, Ron.

Q. And what did you understand the relationship to be between Mr. Zicher and

speaking about in this manner was my second day when I got there, we had an MDA audit -- no -- not audit, she came because there was a complaint about somebody eating a Cheetos product that had caused some type of difficulty to that individual.

So that's one harm.

The harm is, is that if we're not assessing the hazards correctly, you can't put the preventative measures in place to ensure that you're not introducing an adulterated product into the stream of commerce. So that is an irreparable harm to end-users as well as the company because you're in a position where things are going out that you haven't properly assessed.

You're having -- you have customers that have an expectation that their product is being handled in a specific way that meets the rules and regulations on FSMA.

Q. And when you say "FSMA," you mean FSMA?

A. Correct.

Q. And you indicated, in the second sentence, "More specifically for Creative Werks, LLC, this noncompliance creates legal liability and culpability due to our breach of contract, breach of fiduciary duty, and falsifying documents among

other things to our clients, the managing members of Creative Werks LLC, governmental regulatory agencies, and the end-users and society at large."

Okay? Those are your words; right?

A. Uh-huh.

Q. And what breach of contract are you referring to when you were drafting this complaint -- this report?

A. Okay. So, for example, Nestle, they required we follow certain types of sets of guidelines they had implemented in addition to the things that FSMA required us to do. Those things were not being followed or remediated. They didn't have the mechanisms in place to address some of the issues that they had even captured in their own audit report.

The audit report on its face stated that there had been issues of repeat findings of things that were not in line with the guidelines that they had set forth.

First of all, you know, you had mentioned HACCP. So HACCP is not the prevailing standard. HARPC is the prevailing standard. HACCP is a part of the HARPC, but HACCP in itself does not discharge the requirements for the Hazard and Risk

Prevention Control Mechanisms.

So that's an example.

Q. So you mentioned Nestle, and you mentioned that Nestle conducted an audit?

A. That is correct.

Q. Okay. And your opinion is that the results of that audit reflected, in part, a breach of contract by Creative Werks?

A. Well, from my perspective, yes.

Q. Did you review the contract that existed at the time between Creative Werks and Nestle?

A. I did not review the contract, but I spoke with the person, and, in sum, she articulated, you know, the expectations, and based upon the conversation I had with her and the audit report, there was some definite deficiencies and some specific rules that went along with that that was not compliant or had not even been addressed.

Q. Are you referring to an audit conducted by Nestle in 2022 when you were working there?

A. The audit -- that's the audit report that I would be referring to.

Q. Okay. And do you recall what the audit summary was?

A. Not off the top of my head.

safety plan.

Q. Do you recall how many food safety plans were in effect at the time that you worked for Creative Werks?

A. I was only given -- I was given a food -- a food safety plan that was supposed to be the food safety plan template.

Q. Are you referring to the Dunkaroos?

A. Yes.

Q. And so you -- part of your job responsibilities included a review of the Dunkaroos food safety plan?

A. I'm sorry. Are you asking me -- was I supposed to review? Well, yeah, I mean.

Q. In fact, you were told by Mr. Zicher you were supposed to use the Dunkaroos food safety plan to update the other food safety plans that were in effect at the time; correct?

A. No, there were no other food safety plans, I don't believe.

Q. Really?

And what kind of research did you do to determine that there were -- that the Dunkaroos plan was the only food safety plan that was in effect?

A. I looked in all the places that they had provided for me to find this, and he said that the plans -- all I know is that the Dunkaroos was supposed to be the template for the food safety plan.

He indicated that -- I met with him, and he indicated that that was the template that was supposed to be followed for the food safety plan. I met with him, and I asked him -- because I wasn't clear on how he derived at that plan -- what -- yes, I met with him, and I asked him, you know, how did he come to that conclusion, what was the information that he used, the basis of how he formed those.

Q. In fact, when you asked that question of Mr. Zicher, he sent back to you a participant manual with respect to the Preventative Controls for Human Foods under the Food Safety Preventative Controls Alliance; is that correct?

A. I believe that is correct.

Q. What do you understand the FSPCA to be?

A. What do you mean?

Q. In your professional capacity, did you ever come to learn about an organization called the Food Safety Preventative Controls Alliance?

A. Yes.
Q. In fact, that was a manual you studied, wasn't it?
A. When?
Q. When you were taking food safety classes?
A. When I got my PCQI, we reviewed that manual.
Q. Okay. And if I told you that this manual was created by and between three different agencies, one being the FDA, one being the Institute for Food Safety --
A. Can you show me that?
MR. COHEN: Why don't we mark this as Exhibit 9.
THE STENOGRAPHER: We are on 10.
MR. COHEN: 10.
(Whereupon, M. Madison Exhibit 10 was marked for identification.)
BY MR. COHEN:
Q. All right. You've been handed Exhibit Number 10. If you turn to the second page, do you see, on the bottom half, that it says "Hazard Analysis and Preventative Controls for Human Food Training"?

Q. Was there an assertion that the person required medical attention of any kind?

A. I really don't know. I can't remember that.

Q. Okay. And there are corrective actions that are noted in the FDA page 3 that you cited -- correct? -- where the FDA says, quote, "Corrective Actions as provided by the firm (identification of Root Cause)," and there's a chart below that which indicates what action was taken by Creative Werks?

Do you see that?

A. Okay.

Q. Is there anything in this report that indicates that that response was insufficient?

A. Maybe perhaps on page 2.

Q. What is it you see on page 2?

A. Under "Current Inspection," if you look at Number 3.

Q. A note that there could have been a faster response?

A. Yeah, that's the only thing that I've seen.

Q. At this point in time, the product that was the subject of that complaint was no longer being produced at Creative Werks; is that correct?

A. That is correct.
Q. There was nothing to correct at that point -- withdraw that question.
Do you recall what type of product that was? Do you recall that being a Pepsi or Cheetos product of some kind?
A. Yes.
Q. And do you have any knowledge as to why Pepsi at some point discontinued the creation of that product?
A. I'm sorry. Rephrase that again.
Q. Sure. I'll rephrase that.
So you acknowledge at the time of this FDA audit, that the product, that the Cheetos product at issue was no longer being co-packed by Creative Werks?
A. That's what Mr. Zicher said to the FDA.
Q. Do you have any basis to dispute that?
A. I heard him say that it was not being packaged there anymore and/or they had lost a contract or something. I can't remember the exact phraseology, but the sum total of it was it wasn't being --
Q. Do you have any knowledge as to why Pepsi discontinued using Creative Werks to pack those

Cheetos?

A. No.

Q. Did you investigate that?

A. That's all he said.

Q. Well, you indicated, did you not, to Mr. Schroeder, that the Pepsi business was lost as a result of that consumer complaint?

A. I don't necessarily recall saying that.

The conversation that I did have with Mr. Schroeder right after the audit was that he was concerned about the loss of the business to Pepsi, and from my understanding, it was a desire to eventually maybe get that back or recoup that business.

Q. Well, Mary, if I represented that Pepsi discontinued that product, would you dispute that?

A. Yeah, because I see Cheetos products advertised on the market now.

Q. Did you have any firsthand knowledge of what Cheetos product was being co-packed by Creative Werks?

A. No, I didn't.

Q. So you're just assuming it was the same?

A. Not necessarily.

Q. But you have no firsthand knowledge of

what Cheetos product was being co-packed by Creative Werks?

A. They deemed it a Cheetos product and that was it.

Q. You said, in part in your report, "It can be reasonably inferred there is a high probability factor that our noncompliance is a root cause in lost business opportunities such as Pepsi."

So my question to you is what do you base -- this assertion that you made, what did you base -- what research did you do to determine that Pepsi business was lost as a result of noncompliance?

A. I looked at the information that I was given or presented or given access to in regards to how they remediated issues, the records, whatever, templates, plans, or whatever.

Q. Well, you're not saying that you went to go work on remediation of the product that was no longer being packed by Creative Werks; right?

A. So I didn't specifically address the Pepsi issue. However, without reservation, continuous improvement is built on the factors about what led to something else to get you there. So --

Q. So, Mary, what written evidence did you

and this says in here, too, that it was another similar incident like this that had occurred in the same report from the FDA.

Q. Say that again.

A. The report that you presented me with from the FDA, it says somewhere in here -- I briefly read this just now -- that there was a similar complaint to which that was brought up when the FDA investigator came on page 4. So it wasn't a one-off.

Q. You said that -- in your report to Mr. Schroeder that "Noncompliance negatively affects our sustainability, goodwill, and profitability here at Creative Werks."

What type of research did you engage in to determine that there was an impact on Creative Werks' profitability based upon noncompliance?

A. If you lose business, that definitely affects the bottom line. I mean -- I mean, I don't necessarily say that it was affecting -- and if you lose business, that's a lost business opportunity. You lost finances. I mean, that's a reasonable conclusion because that's a lost business.

Q. Mary, can you tell me any instances where

Creative Werks lost business due to noncompliance?

A. Directly, I don't know offhand.

Q. You don't know.

A. But that wasn't the impetus of the situation. The situation is that if you're are not compliant or you are having nonconformances --

Q. Mary, you're not aware of any business that was lost specifically due to noncompliance; correct?

A. I didn't specifically -- I don't think that I specifically said -- I'm saying these things are causative agents of how a business can lose opportunities.

Q. And when you said "If we do nothing, we can expect more of these, and other scenarios, along with an increase in lost revenue, increased legal exposure, and lawsuits, among other things."

A. If you do not remediate your gaps, identify your risks, and try and close those things, you're going to have more of those because you're -- I mean, you're not even aware that something is happening.

I mean, I can't imagine if somebody has a business and you're in business not to make money or to deliver -- I just never got the sense, the

Q. Okay. My question is what efforts did you make to give this risk analysis to Erich Zicher before you presented it to the president?

A. The cacophony of the information that is here -- I spoke to him at various times about these different things. In addition to that -- yeah, I spoke to him about it in...

Q. Mary, tell me what steps you took to give a copy of this risk analysis to Mr. Zicher before you presented it to the president.

A. I did not take any steps to speak to him, but I did reach out to Ms. LeMay to speak with her prior to that, but I was unable to.

Q. And what did you understand Ms. LeMay's job role was in the company?

A. Human resources.

Q. And you considered the risk analysis to be something that would be reviewed by the HR department?

A. I was going to speak to her because I just thought that it was a sensitive matter, and I wanted to get some direction on the situation.

Q. Okay. So, to recap, then, you did not take any actions to give a copy of this report to Mr. Zicher before giving it to the president?

A. In this context -- actually, I followed up -- I had had some conversations with the president before about some of these issues and so --

Q. Mary, it's pretty simple here.

Did you tell -- did you engage in any actions whatsoever to give a copy of your risk analysis to Mr. Zicher before you presented it to the president?

A. Not in its totality.

Q. It's a yes or no question.

Did you give that document -- did you take efforts to give that document to Mr. Zicher before you tendered it to the president?

A. No.

Q. Okay.

A. I did not give him this document in totality, but I had spoken to him about these issues.

Q. But you didn't give him the document; correct?

A. I talked to Mr. Zicher about these various issues in singularity but not in totality as presented to the president.

Q. Mary, we can do this all day. I need a

A. All three.
Q. Okay. Let me ask you this: What is the basis for your belief that you were discriminated against, either for the color of your skin or your sex, whichever, or both?
A. For both. That Mr. Zicher raised these same or similar issues, and nothing happened. I mean, there was no --
Q. So you're saying that Mr. Zicher engaged in activities similar to yours, and he was treated differently?
A. Correct.
Q. And you believe that's because he's a white male?
A. Yes.
Q. Okay. All right. When you say that Mr. Zicher engaged in the kind of -- the same actions that you were perhaps treated differently for, right, is there a specific report or communications that you are aware of that is similar to the risk analysis that you provided to the company?
A. The contents or the context of the information, those things have been discussed or...
Q. Well, I'm just wondering what reports that

Mr. Zicher provided to the company that you think were somewhat similar to the risk analysis report.

A. I'm not speaking about reports. I'm speaking about the context of the information contained in there, the subject matter of that. So that's what I'm speaking of.

Q. Okay. So you're saying that -- to rephrase it -- tell me if I'm right or not -- that Mr. Zicher verbally raised issues that are similar to the issues you raised in your risk analysis?

A. Yes.

And I want to say that maybe there's some written things to discuss, that's issues.

Q. But, as you sit here now, you can't recall a particular writing?

A. That addressed some of these issues?

Q. Uh-huh.

A. Well, not specifically offhand, but there is something where he spoke about deficient food safety plans. I don't know what it is but --

Q. Okay. Well, tell me more about the deficient food safety plans that he communicated to, let's say, the company, in particular, to the president.

A. I'm sorry. Specifically what are you

Q. To whom?
A. To the FDA.
Q. Okay.
A. And they're also -- I had had a conversation with Mr. Schroeder probably the day after this FDA inspection audit complaint follow-up situation that occurred, and we discussed -- he had asked me to ask Mr. Zicher to provide me with some questions we had in regards to this.

We had a brief conversation about the -- you know, some of the issues that were discussed, and I sent out an email addressing the questions and the ask about these different types of deficiencies. So I would have to say that those would be at this time what comes to my mind about the understanding that these -- that there was some issues.

Q. Got to break that down a little bit.

What specifically did you witness Mr. Zicher do on what date that were similar to the statements that you have in your risk analysis?

If you can't recall or you don't know, that's fine, but I need to know.

A. Like I said, there was some things that he communicated during the FDA audit to the FDA person

about Pepsi and the Cheetos and some deficiency and this note in here about, like, some of the recordkeeping and the responsiveness to the complaint.

Q. So other than you understanding Mr. Zicher communicated certain things or understood certain things arising out of the FDA audit, what statements in writing or orally did Mr. Zicher make to the company that are similar to the statements you have in your risk analysis?

A. He writes the issue about the Pepsi, Cheetos in the email communication, I believe, that was sent out right after this audit. I can't -- I don't recall exactly the verbiage, but he raised it.

Q. Are you talking about a summary that he sent out regarding the FDA audit?

A. It was a communication that I can't tell you offhand exactly what. I'll find that at a break.

MR. COHEN: Can you mark this as Exhibit Number 13.

(Whereupon, M. Madison Exhibit 13 was marked for identification.)

A. I don't know. I can't recall but...
Q. You can't recall?
A. No, I can't, but this does discuss --
Q. Mary, what is your understanding of what a Form FDA 483 constitutes?
A. A Form 483 is a formal document that is issued by them in terms of noted violations that they have chosen to formalize on the 483.
Q. And in this case we can agree that the FDA did not issue a Form 483 with respect to this audit; correct?
A. The issuance of a 483 does not obviate that there were not observable infractions.
Q. That's not the question I asked.
A. But that's the answer I'm giving you, sir.
Q. But you have to answer the questions I give you, and that's not an answer to the question I gave you.

The question is the FDA did not issue a Form 483 with respect to the FDA audit we've been discussing; correct?

It's a yes or no.

A. The FDA did not issue a Form 483. However, it does not obviate the fact that there were observable findings, observations made, and

been audited before. So, with that, they institute a measure of watching people to become, you know, compliant. I mean, the objective isn't to just, you know, necessarily give people a 483. Typically, a 483 is something that is either constantly repeated findings, but because they were not ever audited because they weren't registered means that this was the first time that they had --

Q. But if they found material deficiencies, they could have issued a 483? They didn't have to do a second audit; right?

A. They could have, but it's not mandatory.

Q. Well, let me ask you something. Is there anything in this email that was sent out by Mr. Zicher that we were looking at a few seconds ago that is inaccurate with respect to his description of the FDA results?

A. I'm sorry. Say that one more time.

Q. Is there anything that you think is missing or inaccurate with respect to the summary of this meeting that was drafted by -- the audit drafted by Mr. Zicher?

A. Can you rephrase the question?

Q. Yeah. I want to know if this is a fair description written by Mr. Zicher of the FDA audit?

A. I would agree that it's a very, very high-level summary.

Q. Okay. Mary, are you aware of any statements made by Mr. Zicher that the company was -- had potential criminal liabilities with respect to -- let me rephrase that.

Are you aware of Mr. Zicher ever raising the potential of criminal liability with respect to its obligations to comply with the FDA regulations?

A. Yes, he's aware of the statute. We discussed it.

Q. Okay. So who did he assert -- you had a discussion with Mr. Zicher about criminal liability?

A. We talked about the statute.

Q. Okay. I want to know if he had a discussion with you where you spoke and used the word "criminal liabilities"?

A. We spoke about the statute and that there are -- you know, more or less the trouble that you could get into because we had that conversation with Donna because she raised that issue --

Q. She raised criminal liability issues?

A. When we spoke, she was talking about this. She was concerned because she didn't want to get in

trouble or go to jail.

Q. So if we call her as a witness, she'd say she raised the issue of potential criminal liability? This is your testimony today?

A. We spoke in one of our meetings, and she indicated that there was issues, and that she didn't want -- you know, what she actually said was something about an orange jumpsuit or something, and we just kind of laughed it off, but she did, in fact, say that.

Q. I guess we'll find out.

A. Okay.

Q. Let me ask you this question: Are you aware of Mr. Zicher making any statements to the president about potential criminal liabilities?

A. I wouldn't have any knowledge of that.

Q. Are you aware of Mr. Zicher ever submitting a report that indicated inherent systematic failures to comply with FSMA?

A. To whom?

Q. To the president.

A. I really don't have any understanding about what Mr. Zicher -- to the in depthness of what he spoke to or intended to someone else, but I am aware that we discussed that these

deficiencies were there.

Q. So do you know whether or not Mr. Zicher ever reported to the president or others in the company alleging that there was the potential of irreparable harm to Creative Werks' stakeholders?

A. Well, my takeaway from conversation, and specifically dealing with some of this stuff and Nestle, I mean, it was, like, we have to fix these things because it was a problem for our customers.

Q. But what did Mr. Zicher himself say --

(Simultaneous speaking.)

BY MR. COHEN:

Q. -- did he use the term there's the potential of "irreparable harm"? Is that something he said?

A. Well, I would equate, like, making our customers not happy or business issues. There was something that had come up with, I want to say, like, some salmonella situation.

Q. But did Mr. Zicher ever, to your knowledge, communicate to the company that there was the possibility using the terms "irreparable harm," as you used them?

A. So we don't always have to use the same phraseology to mean the same thing.

Q. Of course not, Mary. I know that. I just want to know if you heard that or not. If you didn't hear it, say no. If you did hear it, you can say yes.

A. I already said that I can't speak to whether he used those exact words or not.

Q. Okay. What about -- do you know whether or not he ever submitted a report verbally or in writing to the company asserting that there had been breaches of fiduciary duties?

A. Well, noncompliance.

Q. I want to know if he used the term --

A. I don't know whether he used that term.

Q. Well, I just have to ask this. I have a bunch of these.

A. And I understand, but I'm just saying how he -- my takeaway, and how I phrase it may not be that, but, to me, you have a nonconformance or you have the different things that, like, you repeatedly didn't do, and it's a topic of discussion.

Q. Okay. But, unfortunately, Mary, I have to ask you --

A. No problem.

Q. -- I have some very specific language, and

of that. So it's a little bit more comprehensive than just --

Q. But having a continual improvement methodology in place is a proper goal for a company that's packing food; right?

A. The FDA mandate is risk management, and continual improvement is not necessarily risk management. It's a component, but it's not --

Q. Okay. Mary, are you aware of any instances -- pardon me. My computer is going crazy.

Mary, are you aware of any instances where Mr. Zicher reported to the company that there was falsification of documents?

A. No, I'm not aware.

Q. Are you aware of Mr. Zicher bringing to the attention of the company concerns that he had over the use of an X-ray on a Bartlett line?

A. I know it was something we discussed in the FDA audit, if I'm not mistaken.

Q. Mary, I want to know if Mr. Zicher stated something to the company about his concern over safety with respect to the X-rays.

A. I know it was discussed in the FDA audit, and I can't -- I don't know what he did or didn't

I vaguely recall something in terms of what you're saying to validation of startup, but that is not a preventative measure because you have verification, validation. It's several steps. It's just not that, and if you do it prior to the seasonal startup, you know, what are you doing afterwards.

Q. Mary, did you look at the -- any preventative maintenance documentation associated with a particular X-ray machine that was in use at Creative Werks?

A. From what I understood, there was no preventative maintenance outside of the yearly checkup.

Q. Did you check on the manufacturing side or do any research to determine what would be appropriate preventative maintenance?

A. As I drew to your attention, the FDA guidance says you are in a closed box machine, they recommend periodic --

Q. It's a recommendation or a mandate?

A. Well, FDA guidance is a two-edged sword. They tell you this is what they recommend. You don't have to do any of this. None of it -- they recommend -- all of this is a recommendation because, clearly, even if you -- let's go back to

your exhibit that you gave me from the preventative controls, turn to the second page or third page of the manual. It talks about in addition. It speaks to the fact that these are recommendations. You can choose to do them. You don't necessarily have to, but you have to be able to demonstrate that you comply with the overall --

Q. It's a recommendation, though; right?

A. Uh-huh.

Q. Mary, are you aware of Mr. Zicher ever orally, or in writing, conclude that Creative Werks has year over year consistently been out of regulatory compliance with the FD&C Act?

A. You asked me do I know if he said that?

Q. Yes.

A. No.

Q. Do you know if Mr. Zicher had ever suggested that there is no cognitive recognition that the food safety plans are out of legal compliance with FSMA?

A. Oh, he acknowledged that they were deficient.

Q. But you stated in yours that there was no cognitive recognition that the food safety plans are out of compliance, and now you're testifying,

if I understand you, that he specifically engaged you for the purpose of putting them in legal compliance; right?

So Mr. Zicher had -- isn't it true, based on your testimony, that Mr. Zicher did have a cognitive recognition that the food safety plans were out of compliance?

A. I would not exactly say that.

Q. Well, what exactly would you say?

Because you put --

A. I did, but this document that you gave me here, you said that Mr. Zicher used this to -- was his template. Being deficient doesn't -- being deficient does not -- a deficiency ultimately means a noncompliance of some sort.

Q. So, Mary, you testified today that Mr. Zicher -- because there's testimony that Mr. Zicher hired you in part. To get the food safety plans up to compliance -- correct? -- and you, in fact, worked on that?

A. I was hired to help assist and bring in these things to -- you know what I'm saying? Getting the food safety plans --

Q. Well, but did Mr. Zicher ever tell the company that there was no cognitive recognition

that the food safety plans are out of legal compliance?

A. I have no idea what Mr. Zicher told them.

Q. And, in fact, what did you mean when you -- no.

Are you aware of Mr. Zicher ever reporting the loss of any Pepsi business due to noncompliance issues?

A. When we were in the FDA audit, the first mention I heard of that, he specifically said we -- they lost the business after this situation happened.

Q. Okay. And if I told you that Cheetos discontinued the production of that particular Cheetos Pepsi product, do you have any basis to dispute that statement?

A. If that's what you're telling me today.

Q. And, Mary, what if I were to tell you that the reason that Pepsi discontinued that product was that the packing costs were too high because it was a manual procedure?

Let me rephrase that.

If I were to tell you that Pepsi discontinued that creative packaging with Creative Werks because of the cost of the

methodology being used, would you have any reason to dispute that?

A. To be clear, I have no -- the only understanding that I have was that after this instance happened, they lost the business. That's to the full extent.

Q. So are you aware that Creative Werks asked Pepsi to make a capital contribution to buy more efficient equipment and Pepsi declined to do so? Do you have any basis to dispute that?

A. I don't. I wasn't aware of that if that is the case. I mean, I don't particularly know. I mean all of those are hypotheticals. I don't know.

Q. Do you know if Mr. Zicher ever asserted in writing or verbally to the company that there's been improper interpretation, analysis, and application of relevant statutes?

Are you aware whether he ever made statements to that effect?

A. That there was a -- that -- it was not the proper interpretation of the statutes to what was going on.

Q. Are you aware of Mr. Zicher ever reporting to the company that there had been a failure to

apply relevant statutes, standards, and regulations?

A. Not to the company. However, there was some discussion about the standards, regulations that have been applied.

Q. So the answer is no, you didn't hear him say that or you're not aware that he made those statements?

A. Not to the company, but it was --

Q. That's the question.

A. Yes, to the question, not to the company but there was a discussion about these standards and the application of them. To that, I want to say that I sent out an email that discussed some of the statutes in regards to after the audit happened.

Q. So when you said there was discussion, you mean between you and Mr. Zicher?

A. Yes, and as well as I sent out the email about the --

Q. You sent it?

A. Uh-huh.

Q. Okay.

A. -- in response to what he had written here, I lined up the statute.

Q. And you're referring to what exhibit number?

A. I'm not referring to any --

Q. You just pointed to that document.

A. I'm saying Mr. Zicher -- it -- sent out a communication, and I don't know if it was this, but I want -- it had something to do with the audit. I'm not going say it was this one.

Q. So he had a communication regarding the audit.

A. And in response to that I sent out a detailed email lining up all of the statutes that underscored the issues that were raised during the audit.

Q. Mary, to your knowledge, did Mr. Zicher ever communicate to the company that there is a culture that is diametrically opposed to the transparency mantra of Creative Werks?

A. Mr. Zicher articulated to me, when I asked him for some questions that Mr. Schroeder asked me to ask him for, that -- he just, like, I'm not giving them to you. We -- that's -- I want to say that was the first time I heard Ron's name. He said that him and Ron decided exactly -- well, Mr. Schroeder should know, and so that's -- it's

part of the basis for that statement because it seemed to have gone against the transparency model that the company said that they had or I just really was just trying to provide him with the information that he asked for so that he could understand exactly, you know, what was going on or, you know, really, that's all I was trying to do, give him some answers because he had questions.

Q. You said that there was a culture -- a culture diametrically opposed to the transparency mantra of Creative Werks, and you've just given me what you said was an instance where Mr. Zicher told you something that in your mind was contrary to the transparency mantra; right?

A. While I do understand that you said that there was an instance. Other conduct and other actions pretty much supported that.

Q. Okay. That's what I want to know. So when you said that there's a whole culture opposed to the transparency, can you name ten? Five?

What is it that you can cite specifically -- something you referenced -- that would support there's a culture diametrically opposed to transparency?

A. So, for example, I raised in the -- I'm

A. I was -- Mr. Zicher did not -- I do not recall him telling me specifically to go on there and work through it. How I came to understand about that is I believe that that was a function of the person -- two people, somebody was doing this work. These documents were supposed to be documents that we were supposed to provide to the customer. I cannot recall that I was supposed to remediate the list as you -- are you saying I was supposed to remediate the list?

Q. Yes.

Mr. Zicher instructed you to put effort into responding to outstanding customer document requests; correct?

A. I cannot recall that Mr. Zicher told me that. I just -- I understood from the lady who trained me that we would have document requests and where I should be able to find these documents, but those documents weren't there to respond to the people. I put in all the documents that were available and brought it up to whatever percent, and we were not able to go any further because those documents did not exist.

Q. Mary, in your risk assessment, you indicated that Creative Werks encourages, quote, "a

blatant disregard for the law."

Do you know if Mr. Zicher ever made a statement to that effect to the company?

A. I don't know whether he did or not.

Q. Mary, would you agree if I represented that under the FSPCA protocols that you studied in part, that it defines an audit as a systematic --

A. What --

Q. Page I -- I-9.

And you see it defines audit as a "systematic, independent, and documented examination through observation, investigation, records review, discussions with employees of the audited entity, and, as appropriate, sampling and laboratory analysis to assess an entity's food safety processes and procedures."

Are you familiar with that definition generally speaking?

A. Uh-huh.

Q. Okay.

A. Yes, I am.

Q. So are you familiar with SQF Food Safety Audits?

A. Yes, I used to perform them.

Q. Used to perform them?

A. Uh-huh.
Q. Were you an auditor?
A. Uh-huh.
Q. You were? You were licensed as an auditor?
A. Uh-huh.
MR. COHEN: Okay. And if you could please mark this as 14.
(Whereupon, M. Madison Exhibit 14 was marked for identification.)
BY MR. COHEN:
Q. So, Mary, I just handed you an SQF Food Safety Audit, and this audit indicates that it is a recertification, and that this was an audit that occurred, looks like, March 29, 2022.
And you can see on the certification body and audit team that they spent 23 hours on-site and eight hours writing this report.
Do you see that?
Do you see that?
A. It's written here.
Q. Okay. We just need a verbal answer.
And are you familiar with this type of format as you said you were an auditor yourself?

A. Yes, this is -- it follows the standard.

Q. Okay. And what is your understanding of what an SQF Food Safety Audit is?

A. Well, a safe quality food audit is an audit that comes in, and it evaluates the information that is presented to them. The audit does not either confirm or deny compliance. It just asserts that, to this particular scheme, you have something in place relative to that, but it ultimately -- yeah --

Q. Mary, on the second page of this document, there is a Section 2.4.3 regarding the "food safety plan (Mandatory)."

Do you see that?

A. Uh-huh.

Q. This says, in part, that "There are four safety plans in place for the repackaging of confectionary snacks, grinding coffee, and production of food grade packing materials."

Previously when I asked you if you were aware of any other safety plans, you said that the only safety plan you were aware of was the Dunkaroos plan?

A. Correct.

Q. Do you have any reason to dispute or

Q. Well, you were an SQF auditor; right?
A. It is.
Q. And so you know it's out of a hundred.
A. I do.
Q. Okay.
A. But that's not what it says.
Q. It says --
A. It says 96 --
THE STENOGRAPHER: We do have to do this one at a time, though. I'm sorry.
BY MR. COHEN:
Q. So, Mary, you understand when it says an audit rating of 96, that it's an audit rating of 96 out of 100? Do you have that understanding?
A. Yes.
Q. Okay. And did you say that you were a licensed SQF auditor?
A. I have certification in auditing.
Q. But an SQF certificate?
A. You don't have to have an SQF -- I mean, the fundamentals of the audits are the same. I'm familiar with SQF --
Q. Well, if I were to represent that you have to have a test, an SQF certification test, among other qualifications, do you hold that particular

certificate?

A. I hold the auditor certificate for a food safety quality.

Q. What entity -- what entity certified that?

A. I don't know. I don't know.

Q. Mary, I'll retract that question and just ask you very specifically do you have an SQF auditor certificate?

A. I have a food safety auditor certificate.

Q. Okay. But it's not issued by SQF; correct?

A. No.

Q. Okay. So when you said before you were an SQF --

A. I said I performed SQF audits before.

Q. Okay. And, Mary, tell me what statements you -- if you disagree with these statements. It's a yes or no question.

SQF audits evaluate a food facility's food safety and quality management systems to ensure they meet the requirements of the SQF code and GFSI standards.

Do you agree with that statement?

A. I agree that they -- however, it's not -- I mean, they evaluate what you present them based

with Creative Werks that many of its customers audit Creative Werks?

A. Yes.

Q. Okay. And why do they do that?

A. To make sure that whatever guidelines that they have in place as well as the overarching ones.

Q. Okay. If I told you that in 2022 there were 14 food safety audits conducted by CW clients, do you have any basis to refute that?

A. I have no idea.

Q. Do you understand what a regulatory audit is?

A. Yes.

Q. What is a regulatory audit?

A. Compliance with the regulatory scheme.

Q. With the FDA and FSMA?

A. Yes.

Q. And if I told you that there were two regulatory audits conducted in 2022, do you have any basis to dispute that?

A. Again, I cannot refute or deny. I don't know. The only audits -- the audits I'm familiar with are the ones I was given to help remediate and the issues that were on there that should be in line with maybe the rest of the audits.

Q. When you made judgments about Creative Werks' failure to comply with the regulation guidelines, did you go back and investigate and read any audits that were conducted other than the one audit that you've referred to earlier today?

A. I read some other audits that they have with some other companies.

Q. I'm asking -- did you read the regulatory audits?

A. I didn't see those. However, even though there might have been some regulatory, these deficiencies were what was noted -- what was given to me to remediate. So this is my understanding of the scope of the work.

Q. Okay. I understand you didn't research the prior audits before making judgments --

A. No --

Q. -- the regulatory process?

A. So, no, I researched the information that was given to me and made available to me. I asked, if it wasn't presented, then I had no way of knowing that it existed because I did ask.

Q. Don't you think it would have been relevant for you to read the regulatory audits when

opining about the company's general compliance with FDA regulations?

A. I read the audits. I read what was given to me. I read what I had access to, and, still, even in light of what you're suggesting here, it does not change the fact that you got four -- you got one HACCP plan that deals with the products -- each product isn't the same. Each one has a different inherent risk that is not addressed. It doesn't obviate some of the underlying issues.

Q. Mary, wouldn't you agree that having more information at your fingertips would have been helpful in your assessment of the company's compliance with regulatory schemes?

A. Based upon the list of policies and procedures that were given to me that were supposed to be in place, those are supposed to be the policies and procedures. If they're not there, then reading another -- something that's not part of the actual company's -- I mean, it is a part of the business record. So that's not a precise statement to me, but the information was not presented to me.

Q. Well, Mary, you said --

A. No. You go on.

Q. Mary, you had said that there were instances where you'd go searching around for documents that you wanted to find, and my question is what efforts did you engage in then to go look at prior audits that were either conducted from a regulatory standpoint or from a customer standpoint?

A. I accessed the information that was available to me and made on the links and stuff that was given to me. I was given previous audits by Mr. Zicher to review. I reviewed those. I line balanced them against the policies and procedures. I understood that they had a positive rating for their scores, but I also understood that some of the specific issues that were there highlighted here, like, for example, on this Nestle audit, which we had Exhibit Number 9, that some of the substantive things that needed to support an adequate food safety plan were bereft in what the policies and procedures were.

Q. Well, in that Nestle audit that you have, there's corrective measures that were agreed to and signed off by the company; right?

A. Yeah, they corrected and the dates --

Q. So, then, with respect to the issues that

you said were somewhat noncompliance issues, in cooperation -- those issues in the Nestle report that you say were noncompliance issues were all corrected; correct? Is that right?

A. No. No.

Q. Aren't they signed off there by the Nestle auditor?

A. No.

Q. Well, I'll direct your attention -- here we go. Thank you.

Okay. So if we look at this first page and it's got corrective actions, right, on the top one, for instance?

A. Uh-huh.

Q. And then it says who's the person responsible, and it says Angie. Do you see that?

A. Yes.

Q. And then it says the estimated date is going to be 1 November '22.

What do you understand that to mean? That the corrective actions are going to be completed by that date?

A. Yes.

Q. And there's a status over here that says closed.

Do you see that?

On the right side, same page we're looking at, Mary.

A. Yeah. This is not reflective of the information that I was given.

Q. Okay. So I'm not asking you that.

A. But I'm telling you it is not.

Q. But I'm asking what this document reflects, and this document reflects --

A. So whether this document reflects that it's closed or not, that was an error on my part because I did not review this. So I'm going to have to say that Exhibit 9, I cannot agree -- I mean, like, when I had this, these things were not closed.

Q. Okay. Mary, I'm asking you what the face of this document says and what your understanding of it is. Okay?

So you can make speeches, but it's not going to be admissible. Nothing is like that. So my question is --

A. Okay, I mean --

Q. -- does this document appear to be that the person that audited --

A. I have no idea because this is beyond the

scope of my involvement in it because these things were not closed at that time.

Q. Okay. And I'm asking you --

A. If you look on Exhibit 8, Exhibit 8 does not reflect this -- what you got in Exhibit 9.

Q. Mary, I'm asking you what the face of this document provides, and on its face does it say it was confirmed by who and what and is that the name of the auditor listed?

A. I don't -- I don't know.

Q. Well, you used her name earlier today.

A. Yeah, I mean --

Q. That's her; right?

A. Uh-huh.

Q. She said that she reviewed submitted evidence?

A. I don't know. I can't say what she did.

Q. Well, I just want to know --

A. I can't confirm or deny.

Q. You won't confirm or deny if that's what the document says on its face?

I'm not asking you whether you know it to be true for false. I'm asking you if the document reflects that. Mary, it's a simple question.

A. I know what the question is.

Q. It's not a trick question either. It's so someone reading the transcript can know what's on this document.

A. I can't subscribe to the accuracy of this. So I'm not going to.

Q. Let me ask you this, Mary: Do you have any basis to dispute if I represent that all of the open noncompliance issues raised in the Nestle audit were corrected and approved by Nestle?

A. I don't know.

Q. Okay. If I told you in 2023 that there were 14 food safety audits and two regulatory audits, do you have any basis to dispute that?

A. I have no idea. I wasn't there. I can't affirm or deny.

Q. And if I told you that in 2024 there were 15 customer audits in addition to two SQF audits, do you have any basis to dispute that?

A. I cannot confirm or deny. I wasn't there.

Q. And if I were to tell you that in 2022, 2023, and 2024, there were no audits with any material unsatisfactory compliance issues, do you have any basis to deny that?

A. Yes. The Nestle audit.

Q. The Nestle audit said it was satisfactory

on the cover page. I mean, we just --

A. No, and Exhibit Number 8 --

Q. I'm asking you to look at --

A. -- at the relevant time that I was there, on the first page, it had two major findings about the HACCP itself.

Q. Mary, the cover page of the Nestle audit itself that you have in front of you in color, that cover page says the overall audit rating is, quote, "satisfactory improved"?

A. Okay. It may be satisfactory. However, it does not mean that there were some issues involved. Satisfactory -- it's like you take a test. You may get a final grade, but it does not mean you have mastered all of the information in between there.

Q. No, but we did agree that the third page of this --

A. No, we did not agree. You asserted. You gave some definition. I did not agree.

Q. Yeah, but these are their definitions; right?

A. I don't -- I don't know because I didn't -- I have -- I didn't --

Q. Do you have any basis to dispute the fact

that --

A. I can't confirm or deny.

Q. No, you have to let me finish the question.

Do you have any basis to dispute the fact that Nestle, in its audit, defines satisfactory as, quote, "The audit results identified a few issues in need of attention, but none shows significant or fundamental weakness in controls, compliance, or operations."

Do you have any basis to dispute that is Nestle's definition of the word "satisfactory"?

A. I cannot either affirm or deny that statement.

Q. Do you have any basis to dispute that, as a business strategy, after receiving a satisfactory rating, Nestle's instructions are, quote, "continue to conduct business as usual and close gaps"?

A. I cannot affirm or deny that statement either.

Q. You don't have any basis. Okay.

(Whereupon, M. Madison Exhibit 20 was marked for identification.)

really important with respect to an FDA audit is the materiality of the noncompliance issues that are reflected?

A. I don't quite agree with that assertion.

Q. Great. Okay.

In here, under "Internal Audits," it's indicated that "I asked Mr. Zicher if the firm performs internal audits, and he responded yes. He told me the firm does not share these documents. This information was not verified."

Mr. Zicher also told you, I believe in your presence, that there were certain documents he didn't want to provide to the FDA -- correct? -- during the audit?

A. Yes, there were some documents he declined to provide.

Q. And he showed them an electronic copy, however, of a customer complaint that they wanted information about; right?

He brought them to the computer and let them view it on a computer screen?

A. I'm sorry. What are you asking me?

Q. When they asked for a particular document from Mr. Zicher, didn't he say, "I'll show you an electronic copy of it, but I won't give you a hard

copy"?

A. No, he initially refused, period, and then he eventually showed whatever the document was.

Q. So he gave it to them. You're saying he initially refused, but then he capitulated, and he showed the FDA inspector --

A. Whatever.

Q. -- the document electronically; is that correct?

A. Yes. I believe it was in the other report.

Q. And when there's a section of the FDA audit that's called "Refusals," and he stated "I did not encounter any refusals during this inspection," do you have any basis to dispute that?

A. I wasn't a part of this one, 12-22, but there was a refusal when I was there.

Q. But then he capitulated and showed it to him electronically. You said that. You said he initially refused, and then he eventually showed it to him electronically; isn't that correct?

Are you denying that? Which version?

A. I didn't say that it wasn't. I told you that he refused, and then he eventually showed her whatever the document was.

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

MARY MADISON,	)	
	)	
Plaintiff,	)	No. 23-cv-16476
v.	)	
	)	Hon. Manish S. Shah
CREATIVE WERKS LLC,	)	
and STEVE SCHROEDER, Individually	)	
	)	
Defendants.	)	
	)	

Exhibit 2

Table of Contents

Summary

This pre-announced comprehensive routine surveillance inspection of a warehouse, packer/repacker, labeler/Relabler and distribution center (DC) was performed as part of HAF 6 EAST FY-2022 Workplan in MARCS/eNSpect as OP ID-#226878. This

inspection was accomplished utilizing CFR-21, Part 117 – Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventative Control for Human Food – Subparts A, B, and F along with Compliance Program 7303.040, Preventive Controls and Sanitary Human Food Operations. In addition to CP 7321.005 Domestic NLEA and General Food Labeling Program.

Creative Werks LLC functions as a warehouse, packer, repacker (Co-Packer), labeler, Relabler, and DC. The firm's top three customers are (b) (4) (b) (4). The firm's top three products at this location are (b) (4) (b) (4).

This firm store, packs/repacks (Co-Packs), labels/relabels a variety of wrapped and unwrapped ready-to-eat food products per their customer request. After packing/repacking, labeling/relabeling and final packaging is completed, the finished product is scheduled to be shipped to one of their customers distribution centers as specified by their customer.

Previous inspection

The firm has never been inspected by the Agency. This was the firm's initial inspection.

Current Inspection

This inspection was classified as NAI. Although, the firm was not issued an FDA Form 482 at the close of this inspection. The following concerns were discussed in detail with management as follows:

1. I observed light seeping through dock door #5 during the walk-through.
2. I observed that the firm is not consistent with recordkeeping after reviewing training documents.
3. I observed that the consumer complaint investigation for consumer complaint #170623 should have had a faster response.
4. I observed that the firm's pest control activities are inconsistent and needs work.
5. I observed a production employee cleaning equipment located along the north wall adjacent to Production Line (b) (4) with a long white towel using his right hand to touch the floor for balance and alternating the towel in his right hand as he cleans the conveyor equipment on top.

Management Response:

Mr. Zicher promised to make corrections to the observations as soon as possible.

This inspection focused on the following areas: Sanitary Transport, Sanitation, Raw Materials, Recalls, Customer Complaints, Pest Control, Quality Control, Sales, Production, Purchasing, Recordkeeping, and Employee Training.

I did not notice any avian, insect and/or rodent activity during the inspection.

I did not take any samples and/or photos during this inspection.

(b) (3) (A)

I did encounter one refusal during this inspection which converted to an electronic view of consumer complaint #170623 for closure.

Consumer Complaint #170623 Follow-up – (b) (4) (b) (4) Cheese Snacks- 20 ounce (1.4 rigid plastic container with screw chalking). Product of (b) (4)

Consumer Complaint: This consumer complaint dealt with a consumer becoming ill after consuming (b) (4) Cheese Snack. The customer identified a black substance found around the lid as mold.

Corrective Actions as provided by the firm (Identification of Root Cause):

Issues	Resolution	Date Accomplished
Slippage experienced with the lid torque.	Custom built machine chuck was installed to replace the silicone rubbing head & reduce any slipping in the lid application.	3/22/2021
Multiple passes with a barrel through the induction sealer caused burning of the film stock.	Production Team discontinued sending barrels through the sealer more than once.	5/20/2021
Settings for induction sealing equipment not documented.	Documented settings were recorded & posted on the line for the Maintenance Team.	6/6/2021
Reject cylinder & rails caused barrels to jam.	Section of rail was removed to prevent jars & counting sensors was relocated.	6/7/2021
Lid cocked sensor process had poor repeatability.	Adjusted & documented location of cocked lid sensor. Tested in various orientations.	6/6/2021

Additional Complaints: According to Mr. Erich P. Zicher, Director of Food Safety the firm had only one similar complaint sent by (b) (4) on March 13, 2022 regarding a burnt seal. In addition, Mr. Zicher told me he was not aware of any other complaints.

Findings: According to the firm's findings the induction seal for the lid was burnt due to multiple entries of the lid passing through the induction (heat) sealer. It was documented that during manual application of the lid the firm experienced jams on the production line which also resulted in burnt lids.

Packaging Procedure: The packaging procedure for this product was modified on May 20, 2021 as document in the firm's step-by-step corrective actions/investigation listed above.

Preventive Controls: The firms preventive control consisted of the removal of manual application of the lid to a (b) (4) lid application to remove the variation out of manually applying the lid. According to the firm the new machinery was approved by (b) (4)

Product's Current Disposition: According to Mr. Eric P. Zicher, Director of Food Safety, the firm currently is not repacking (b) (4) Cheese Snacks for (b) (4). The contract for packing this product is stagnant until there is a negotiated procedure for lid application for this ready-to-eat product.

Administrative Data

FMD-145

A copy of this EIR should be sent to the individual listed below:

Mr. Erich P. Zicher, Director of Food Safety
Creative Werks, LLC
1460 Brummel Avenue
Elk Grove Village, IL 60007
Email address: ezicher@cwerksglobal.com

Inspected Firm: Creative Werks, LLC
Location: 1350 Munger Rd.
Bartlett, IL 60103

Phone:	(630) 860-2222
Fax:	None
Mailing Address:	1460 Brummel Avenue Elk Grove Village, IL 60007
Email Address:	ezicher@cwerksglobal.com
Dates of Inspection:	September 28, 2022 & September 29, 2022
Days in Facility:	2-Days
Participant:	Clotia C. Abbey-Mensah, Investigator

On September 28, 2022 I presented credentials and issued an FDA Form 482 Notice of Inspection to Mr. Eric P. Zicher, Director of Food Safety who identified himself as the person most-in-charge. We were joined by Ms. Angela K. Knabe, Quality Regulatory Manager, Ms. Anupam (N.M.I,) Sharma, Food Safety & Quality Manager, and Ms. Mary D. Madison, Quality Regulatory Manager. Throughout this inspection I was provided documents for review as requested by Mr. Zicher and Ms. Sharma. I was accompanied on a tour of this facility by Mr. Zicher and Ms. Sharma.

History

Creative Werks is located at 1350 Munger Rd. in Bartlett, IL 60103 in DuPage County. The firm is owned by Mr. Steven A. Schroeder, President. I asked Mr. Zicher if Mr. Schroeder maintain an office at this location and he responded no. The firm has been in business since 1999 and at this location since May 2015.

The firm is (b) (4) square feet (sq. ft.). Of this square footage (b) (4) is considered manufacturing per Mr. Zicher. This firm store, packs/repacks, labels/relabels a variety of wrapped and unwrapped ready-to-eat food products per their customer request.

The firm's telephone is (630) 860-2222. The firm has (b) (4) employees at this location. This number includes hourly, salary and temporary employees per Mr. Zicher.

The firm has two other locations as listed below:

Headquarters/Production Facility	Warehouse/Production Facility
Creative Werks, LLC	Creative Werks, LLC
1460 Brummel Avenue	222 Sievert Court
Elk Grove Village, IL 60007	Bensenville, IL 60106

The firm's office hours are 8:00 am to 5:00 pm Monday – Friday. The firm's production hours are (b) (4) according to Mr. Zicher. The shifts are scheduled as follows:

(b) (4)

The firm runs manufacturing and co-packing on al (b) (4) shifts per Mr. Zicher. The firm does not have scheduled shutdowns for preventative maintenance. According to Mr. Zicher one of the firm's main functions is private labeling.

The firm's FY starts on January 1st and ends December 31st annually. The firm's website is www.creative-werks.com. The firm's email address is ezicher@cwerksglobal.com.

Interstate (I.S.) Commerce

I asked Mr. Zicher what percentage of the finished products at this location cross state lines. He responded (b) (4). I asked what percentage of the finished product is sold wholesale. He responded (b) (4). Lastly, I asked what percentage of components are received through interstate and he responded (b) (4). I requested a copy of a BOL for (b) (4) which was not provided.

The firm does business with their customers Distribution Centers (DCs) domestically and internationally as listed:

1. California
2. Georgia
3. Indiana
4. New Jersey
5. Pennsylvania
6. Texas

7. Utah
8. Wisconsin
9. Alberta – Canada (Calgary)
10. Ontario – Canada (Brampton)
11. Ontario – Canada (Mississauga)

Jurisdiction (Products Manufactured and/or Distributed)

This firm packs/repacks, labels/relabels a variety of ready-to-eat food products such as chocolate candy, cereal, chewing gums and snack foods etc.

Individual Responsibilities and Persons Interviewed

On September 28, 2022 I presented credentials and issued an FDA Form 482 Notice of Inspection to Mr. Eric P. Zicher, Director of Food Safety who identified himself as the person most-in-charge. We were joined by Ms. Angela K. Knabe, Quality Regulatory Manager, Ms. Anupam (N.M.I,) Sharma, Food Safety & Quality Manager, and Ms. Mary D. Madison, Quality Regulatory Manager. Throughout this inspection I was provided documents to review as requested by Mr. Zicher and Ms. Sharma. I was accompanied on a tour of this facility by Mr. Zicher and Ms. Sharma. I requested a copy of the firm's organizational chart during this inspection. (See Exhibit #1)

Responsibilities:

Mr. Eric P. Zicher, *Director of Food Safety*

- Food Safety & Quality
- Escalates Issues
- Environmental Issues
- Projects – (Ongoing, New)
- Identifying Potential Quality Risks
- Microbiological Aspects with Products
- Write SOPs (Work Instructions, Policies, etc.)
- Hire/Fire
- Strategic Directives for Container Safety
- Food Safety & Quality
- Time with firm: 1.9 years
- Time in current position: 1.9 years
- Direct Reports: [redacted]
- Reports to: Mr. Ronald Sammeth, *Chief Operating Officer*

Ms. Angela K. Knabe, *Quality Regulatory Manager*

- Audits (Clients POC for Audits)
- Lead Good Manufacturing Practice (GMPs) Walk
- Ensuring Compliance (Corrective Actions)
- Vendor Approvals
- Quality Management Systems - (PCQI)
- Time with firm: 3.5 years
- Time in current position: 2 years
- Reports to: Mr. Eric P. Zicher, *Director of Food Safety*

Ms. Anupam (N.M.I,) Sharma, *Food Safety & Quality Manager*

- Discussion of Food Safety holds with Sales Personnel
- Certificate of Analysis (COA) Reviews
- Packaging Reviews
- Raw Materials Packaging; Film Review
- Hold Releases
- Operational aspects within Specifications
- Timecards
- Employees Issues
- Releasing product after review of COA
- POC for Food Safety /Food Compliance
- Assist with SOPS by other departments
- GMP Training provided to Operations, Sanitation Materials Handlers and Quality Control Employees
- Sending out samples for testing
- Time with firm: 1 year
- Time in current position: 1 year
- Direct Reports: [redacted]
- Reports to: Mr. Eric P. Zicher, *Director of Food Safety*

Ms. Mary D. Madison, Quality Regulatory Manager

- Audits (Clients POC for Audits)
- Lead Good Manufacturing Practice (GMPs) Walk
- Ensuring Compliance (Corrective Actions)
- Vendor Approvals
- Quality Management Systems - (PCQI)
- Time with firm: 2 days
- Time in current position: 2 days
- Reports to: Mr. Eric P. Zicher, *Director of Food Safety*

Firm's Training Program

I asked if the firm provide any training to their employees and the response was yes. Training is provided to employees upon hire and annually. Ms. Sharma told me that the firm use (b) (4) software for training. The software divides the various training modules into specific topics such as Food Safety, Foodborne Illnesses, Guidance Principles etc. I asked Ms. Sharma if the employees sign-off on training and she responded yes. During this inspection I randomly reviewed employees training records that appeared to be adequate except the firm's recordkeeping is not consistent. All employees do not consistently sign-off on training records as required in their own procedure with a signature and date, which is deemed an official document. This observation was shared with Ms. Sharma during this inspection. This was an observation previously observed at the firm's Elk Grove Village facility.

I requested a copy of management training records during this inspection. (See Exhibit # 2)

Manufacturing Design Operations

This firm packs/repacks and labels/relabels ready-to-eat products such as candy, cereal, cookies, and gums, etc. for their clients.

Donning Area/ Handwashing Station

Prior to entering the manufacturing area, a visitor is required to wear the following PPE: hairnet, ear plugs, laboratory coat, safety vest and safety googles. The firm identifies individuals in production as follows:

(b) (4)		
Management	Visitors	Quality Control

After donning is completed, you proceed to the handwashing station, located adjacent to the employee's break room.

Ambient Warehouse

The firm's warehouse aisles on the south-side mid-way are labeled (b) (4) The north-side of the aisles are labeled (b) (4)

Dock Doors

The firm has (b) (4) dock doors at this location. Two of the (b) (4) are not in use. Dock Door (b) (4) contains the firm's compactor. Dock Door (b) (4) is used to store equipment. The firm's dock doors are grouped into (b) (4) as follows: (b) (4) and (b) (4). I observed that dock door #5 has sunlight seeping in. I shared this observation with Mr. Zicher and Ms. Sharma during the walk-through.

Production Area

The firm has (b) (4) active production lines. Currently the firm is actively using (b) (4) production lines. Some production lines are in segregated rooms. Some production areas can have several production lines packing a variety of products in the same room.

The firm's sanitation area is (b) (4). I observed a walk-in equipment washer from the outside looking in. The doors to this area were locked but I could see from the outside mostly covered cleaned production parts and equipment.

Lines (b) (4) – Repacking

I observed a production employee cleaning equipment located along the north wall adjacent to Production Line (b) (4) with a long white towel using his right hand to touch the floor for balance and alternating the towel in his right hand as he cleans the conveyor equipment on top. This observation was immediately shared with Mr. Zicher and Ms. Sharma during the walk-through. I noticed a similar action with a production employee at the firm's Elk Grove Village location.

This area is also used for storing production equipment and supplies.

I observed (b) (4) packed on these lines in a clear plastic holiday cane. (See Exhibits #3-5)

Sanitation Area

In the next section of the contained sanitation area, I could see compartment sinks. I observed a (b) (4) compartment sinks. I asked what the (b) (4) compartment sink is used for. I was told it is used for washing and sanitizing. There appears to be no rinse step for the (b) (4) compartment sink. I could also see (b) (4) frosting pump equipment through the exterior sight windows.

The east wall in this area houses the maintenance department, and employee entrance.

Line (b) (4) – Whole Packing

I observed (b) (4) Tubes packed on this production line.

Line (b) (4) (Naked)

I observed naked (unwrapped) candy been packed in tubes on this production line. The tubes are equivalent to clear plastic candy canes.

Line (b) (4)

I observed (b) (4) been packed in the cereal room.

Lines (b) (4) Line)

I observed (b) (4) candy containing peanuts repacked on this production line. The firm only runs peanut production on these lines.

Line (b) (4)

This line packs chewing gum. It was currently not in operation during the walk-through.

Lines (b) (4)

I observed (b) (4) packed on these lines in a clear plastic holiday cane.

HACCP Plan

I asked Mr. Zicher if the firm has a HACCP Plan and he responded yes. Ms. Angela K. Knabe, Quality Regulatory Manager is responsible for the firm's Quality Management System (QMS). Time did not permit me to verify the firm's entire food safety plan during this inspection. Ms. Knabe identified herself as the firm's PCQI. This responsibility will soon be delegated to Ms. Mary D. Madison because Ms. Knabe is leaving the firm next week. The firm also have x-ray equipment in place as a process preventive control.

Metal Detectors

The firm documents their metal detector every (b) (4). This information was not verified. This is the firm's only critical control point (ccp) in their process. The firm's metal detectors are calibrated by (b) (4). located at (b) (4) (b) (4). Their telephone number is (b) (4). The firm's website is (b) (4).

Leak Detector

I asked Mr. Zicher if the firm performs leak detection at this facility and he responded yes. The leak detection is performed on the cereal production line. This information was not verified.

Raw Materials

The firm's raw materials consist of clear plastic candy canes, cane handle, product labels for packaging, wrapped candy products, plastic bags, cereal bowls, cardboard boxes, etc.

Allergens

I asked management if the firm has any allergens onsite and their response was yes. The allergens consist of eggs, wheat, soy, dairy, peanuts, and tree nuts per Ms. Sharma. The firm may handle allergens contained in wrapped or unwrapped packaging. I asked Mr. Zicher what preventive controls are in place to prevent cross contamination. He responded sanitation is used to prevent cross contamination and production takes place in cycles. The firm also performs ATP swabbing prior to production per Ms. Sharma. This information was not verified.

Internal Audits

I asked Mr. Zicher if the firm performs internal audits, and he responded yes. The firm performs internal audits annually. This information was not verified. In addition, Ms. Knabe told me that she leads GMP (b) (4) walking audits of the facilities and Food Safety meetings.

Sanitation

I asked Mr. Zicher if the firm has a Sanitation Standard Operating Procedure (SSOP) and he responded yes. I randomly reviewed the firm's SSOP- #6.15 effective June 21, 2022, and it appeared to be adequate. I asked who provides sanitation training and I was told Supervisors, Assistant Supervisors and Team Leads.

Sanitary Transport

The firm has a sanitary transport SOP WI-5,2 that includes (b) (4)-conditions which is uploaded into their database via their (b) (4) software. After review of the firm's sanitary transport SOP, it appears to be adequate.

Logistics

The firm's customers broker trucks for transporting their products. The customers arrange product loads inbound and outbound of their facility. Some customers use their own fleet of trucks. Regardless per Mr. Zicher the truckers must make appointments for pick-ups and deliveries.

Environmental Controls

I asked management if the firm has an environmental control program, and the response was yes. I reviewed the firm's SOP and it appeared to be adequate. The firm's program is sectioned into (b) (4)-Zones. Zone (b) (4) (food contact surfaces) per Ms. Sharma is cleaned and sanitized. The firm sends out samples for APC and E. coli as validation for sanitation. Zones (b) (4) are swabbed with sponges and sent out for Salmonella and Listeria species testing. The samples are sent to (b) (4) (b) (4) located in (b) (4) I asked who performs the swabbing and Ms. Sharma responded the Quality Supervisor, Team Lead and Quality Manager.

Water

I asked Mr. Zicher if the firm monitor the water for the city of Bartlett. Mr. Zicher responded yes. A copy of the city's annual test results was shared on the firm's overhead screen. Additionally, the firm collects and sends out (b) (4) water samples for Heterotrophic and coliforms.

Refuse

The firm's refuse is serviced by (b) (4) is located at (b) (4) (b) (4). The firm's telephone and website are (b) (4) and (b) (4) respectively.

The firm's recyclables and landfills are also maintained by (b) (4). The recyclables consist of corrugated and plastics polymers such as (b) (4).

Manufacturing Codes

I asked Mr. Zicher to decipher the firm's manufacturing code as follows:

(b) (4)

(b) (4)

(b) (4)

Complaints

I requested a copy of the firm's consumer complaint procedure during this inspection for review. The firm's consumer complaint is identified as WI-2.6 with an effective date of May 21, 2019.The firm's complaint procedure appears to be adequate. I asked Mr. Zicher if the firm performs trending, and he responds yes. Because the firm co-packs for their clients there is a relationship between Creative Werks Quality personnel and their client's Quality Contact per Mr. Zicher. I asked how investigations are performed. Mr. Zicher told me that after an investigation is completed a corrective action is provided when the root cause is determined.

Recall Procedures

The firm has a recall procedure reference as Traceability. According to Ms. Sharma the firm performs trackabilities (b) (4) . I randomly reviewed the procedure, and it appears adequate. I asked management if the firm performs Mock Recalls and Ms. Sharma responded yes. This information was not verified. She told me that the firm performs traceback and trace forward.

Objectionable Conditions and Management Responses

The following members of management were in attendance during the close-out meeting: Mr. Eric P. Zicher, Director of Food Safety, Ms. Anupam (N.M.I,) Sharma, Food Safety & Quality Manager, and Ms. Mary D. Madison, Quality Regulatory Manager. In addition, we were joined by Mr. Ronald Sammeth, Chief Operating Officer on the telephone. This inspection was classified as NAI. Although, the firm was not

issued an FDA Form 482 at the close of this inspection. The following concerns were discussed in detail with management as follows:

1. I observed light seeping through dock door #5 during the walk-through.
2. I observed that the firm is not consistent with recordkeeping after reviewing training documents.
3. I observed that the consumer complaint investigation for consumer complaint #170623 should have had a faster response.
4. I observed that the firm's pest control activities are inconsistent and needs work.
5. I observed a production employee cleaning equipment located along the north wall adjacent to Production Line (b) (4) with a long white towel using his right hand to touch the floor for balance and alternating the towel in his right hand as he cleans the conveyor equipment on top.

Management Response:

Mr. Zicher promised to make corrections to the observations as soon as possible.

Refusals

I did encounter one refusal during this inspection which converted to an electronic view of consumer complaint #170623 for closure.

General Discussion

I requested a copy of the firm's Consumer Complaint Procedure. Instead, I was provided a copy of the firm's Customer Supplied Materials Procedure via email on September 28, 2022. (See Exhibit #6) I reviewed this procedure, and it was not easy to read or understand. N.B.-This procedure revision numbers are incorrect and annual reviews list the same revision numbers although they were reviewed in completely different years. The current revision number should be 12 instead of 6.

Revision Number	Effective Date	Revision Log	Approved By	Approved Date
4.0	9/15/11	AR/NC	(b) (6)	9/14/2011
4.0 = 5.0	11/26/12	AR/NC		11/24/12
4.0 = 6.0	02/21/14	AR/NC		2/19/14
4.1 = 6.1	4/07/14	Changed Procedure		4/5/14
6.0 = 12	07/22/21	Updated	Erich Zicher	07/16/21

Ledger: AR = Annual Review; NC = No change

Additional Information

Pest Control

The firm's pest control is monitored by (b) (4) is located at (b) (4). Their telephone number is (b) (4)

The firm is concerned with rodents and insects. The firm's preventive controls consist of (b) (4) traps, (b) (4) and (b) (4) traps. I randomly reviewed the firm's pest control records from January 2022 to August 2022.

The firm's pest control records indicated that there is no consistent follow-up between the firm and the pest control technician after the service is completed. This issue appears to be ongoing for quite some time. I asked Mr. Zicher if the firm has considered replacing this pest control company due to a lack of genuine service capabilities. Mr. Zicher responded that it has been considered.

Parking/Entry:

FYI! - The facility's visitor's parking is limited. In addition, the signage for visitor's parking is in an inconspicuous location. It's attached to the entry area façade of the building much higher than normal posting therefore, making it easy to overlook. NB: Prepare to locate available parking anywhere in the firm's parking lot.

The entry area is a virtual set-up. If you are equipped with the Director of Food Safety's cell number, please use it for prompt entry.

Food Defense:

The firm's culture regarding Food Defense consists of "see something, say something" per management. In the firm's employee badging and entry area the firm is equipped (b) (4) (b) (4). But the main entry into the building (b) (4) (b) (4). On September 28, 2022, I was allowed entry into the facility without signing in because there were no sign-in sheets available. I was told its okay. On September 29, 2022, the same scenario, I told the escort there were no sign-in

sheets available. This time that individual returned with a sign-in sheet. The firm's business entry is easily accessible due to (b) (4) through the lobby door. Management should be aware and concerned about who enters their facility and their whereabouts upon entry.

Samples Collected

I did not take any samples and/or photos during this inspection.

Voluntary Actions

I did not witness any voluntary actions during this inspection.

Exhibits Collected

1. Organizational Chart
2. Management Training Certs – 3 pages
3. (b) (4) – 2 pages
4. (b) (4) Labels
5. (b) (4) Candy Wrappers
6. Consumer Complaint Procedure (Customer Supplied Materials) – 3 pages

Attachments

1. FDA Form 482 Notice of Inspection dated September 28, 2022 – 3 pages

10/18/2022

X Clotia C. Abbey-Mensah

Clotia C. Abbey-Mensah

Signed by: Clotia C. Abbey-mensah -S

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

MARY MADISON,	)	
	)	
Plaintiff,	)	No. 23-cv-16476
v.	)	
	)	Hon. Manish S. Shah
CREATIVE WERKS LLC,	)	
and STEVE SCHROEDER, Individually	)	
	)	
Defendants.	)	
	)	

Exhibit 3

From: Erich Zicher[/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=8869B5871C2245A09D77CB6A5AA04269-ERICH ZICHE]

Sent: Wed 9/28/2022 10:17:46 PM (UTC)

To: Erik Peterson[epeterson@cwerksglobal.com]; Ulises Rodela[urodela@cwerksglobal.com]; Mart Brosas[Mbrosas@cwerksglobal.com]; Tim Boyd[tboyd@cwerksglobal.com]; Anupam Sharma[asharma@cwerksglobal.com]

Cc: cwerks_salaried_associates[cwerks_salaried_associates@cwerksglobal.com]; Angela Knabe[aknabe@cwerksglobal.com]; Mary Madison[mmadison@cwerksglobal.com]

Subject: Bart FDA Routine Inspection - Day 1

Hello Team,

I wanted to provide a quick recap on today's FDA inspection. The inspector has concluded for the day and will be returning tomorrow to finish her review and walk the floor. High level summary of today as follows:

- Inspector arrived at 2:05 PM, 482 – Notice of inspection was provided to myself
- General site summary information was verbally provided
- Interviews Conducted
- Training Program Summary
- Trace/Recall WI
- Inspector concluded for the day at approximately 4:30 PM

The inspector did also spend a fair amount of time today following up on a complaint that was reportedly filed with the FDA pertaining to the PepsiCo Chester Paw product. PepsiCo and CW do not have record of such a complaint, but collaborating with PepsiCo, we were able to communicate our investigation details and corrective actions based upon the reported nature of the complaint (no records were physically shared with the inspector).

Please let me know should there be any specific questions or concerns.

Best,

[[#]]
name: Erich Zicher
mobile: 847-826-9424
[[#]]

Message

From: Erich Zicher [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=8869B5871C2245A09D77CB6A5AA04269-ERICH ZICHE]
Sent: 9/30/2022 2:37:40 AM
To: Anupam Sharma [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1a1f86487e5640f2b94906dcacb1b4db-Anupam Shar]; Angela Knabe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12e3c66a3f9240f49244dd2f43dc3f05-Angela Knab]; Mary Madison [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb6c19e0fbc447f2bba7f81a69088eb2-Mary Madiso]; Patrick Woodward [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9af0c6cc0b624e1684367f5b66f4b683-pwoodward@c]; Wendy Proulx [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6be4922011dc41db8b28150dbfe97f0a-Wendy Proul]; Billy King [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e7ae719d39f7482cba50bfa24df873c3-Billy King]; Teresa Noles-Puccio [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbd110e96b97493fa14073727798a02d-tnpuccio@cw]; Ronald Sammeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d101e6ad5e1646b7a3e9658b45741cdb-Ronald Samm]; Steve Schroeder [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=576157045b2e4cfd8f668b80846d752d-sschroeder@]; Jürgen Peters [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7ffe8a4dd39045438bb5479f3f0cff6e-jpeters@cwe]; Doug Mauger [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f9c78d76045649d8a2d7dc6da299b21e-dmauger@cwe]; Gretchen LeMay [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ecac537a42344283ba12d9065b1b401e-Gretchen Le]; Erik Peterson [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a8a34be6a21849e0a396d416aed069e1-Erick Peter]; Ulises Rodela [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=13f3ff935c034511ad33438ce28b1179-urodela@cwe]; Mart Brosas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=61c8caf58b83438989eac3cede9fdc0c-Mart Brosas]; Tim Boyd [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fca1abc2e2a14cf7920bb81e8c259070-Tim Boyd]
CC: cwerks_salaried_associates [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb5f7fbf66e24ea6b93f183a438c8d0d-cwerks_sala]
Subject: FDA Inspection Routine Inspection - Day 2

Hello Team,

We concluded our FDA inspection earlier this evening. High level summary of today's visit is as follows:

- Inspector arrived at 12:40 PM
- Rereviewed the complaint related to PepsiCo that was discussed yesterday
- Confirmed our refuse hauler information was consistent with Bru
- Review of Pest Control Records
- Review of Sanitary Transit Records
- Review of Food Safety Plan Process Flow Diagrams
- Review of Environmental Monitoring and Water Testing
- Review of Sanitation Processes
- Discussed Label Control
- Tour of Bartlett (Details in Closeout Meeting Observations)
- Inspector Reviewed Details of Packaging Sample Collected
- Inspector Performed Closeout Meeting (Details in Closeout Meeting Observations)

- Inspector concluded at approximately 6:25 PM

Closeout Meeting

Attendees:
- Ron Sammeth
- Erich Zicher
- Anu Sharma
- Mary Madison

Feedback: no 483's were issued for the visit. The below were discussion points that the inspector indicated will be included in the report:

1. Doc review: Pest control records demonstrated that our service provider needs to improve upon their communication
2. Doc review: Consistency of manual training records was mentioned pertaining to the printing/signing/dating of recipient names
3. Walk: Dock door #5 had light showing at the base of the door
4. Walk: EE cleaning LN 7300 was witnessed touching the floor and then using same hand to continue cleaning
5. Pepsi Complaint: Concern over lack of urgency in addressing the referenced FDA complaint (complaint received from PepsiCo: 5/28/21, CA completed by CW: 6/7/21, date of FDA referenced complaint: Oct. '21)

I would like to thank the Bartlett Leadership Team for their efforts in supporting this visit. The site showed extremely well, aside of the two observations noted by the inspector. I would also like to express my appreciation for @Anupam, @Angela, @Mary, @Patrick, @Wendy, @Teresa, @Billy, all whom supported various parts of the inspection and document review. Thanks also for @Ronald in being available for both escalations during the inspection and being able to join in at a moment's notice for the closeout meeting.

Me and my team will be reaching out to clients as required per their respective quality manuals to inform them of the visit. Please let me know should there be any questions.

Best,

creative werks

Erich Zicher
Director of Food Safety

1470 Brummel Ave.
Elk Grove Village, IL 60007
+1-630-509-3087 *(office)*
+1-847-826-9424 *(mobile)*
creative-werks.com

Message

From: Mary Madison [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=FB6C19E0FBC447F2BBA7F81A69088EB2-MARY MADISO]
Sent: 9/30/2022 7:53:23 PM
To: Erich Zicher [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8869b5871c2245a09d77cb6a5aa04269-Erich Ziche]; Anupam Sharma [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1a1f86487e5640f2b94906dcacb1b4db-Anupam Shar]; Angela Knabe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12e3c66a3f9240f49244dd2f43dc3f05-Angela Knab]; Patrick Woodward [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9af0c6cc0b624e1684367f5b66f4b683-pwoodward@c]; Wendy Proulx [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6be4922011dc41db8b28150dbfe97f0a-Wendy Proul]; Billy King [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e7ae719d39f7482cba50bfa24df873c3-Billy King]; Teresa Noles-Puccio [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbd110e96b97493fa14073727798a02d-tnpuccio@cw]; Ronald Sammeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d101e6ad5e1646b7a3e9658b45741cdb-Ronald Samm]; Steve Schroeder [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=576157045b2e4cfd8f668b80846d752d-sschroeder@]; Jürgen Peters [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7ffe8a4dd39045438bb5479f3f0cff6e-jpeters@cwe]; Doug Mauger [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f9c78d76045649d8a2d7dc6da299b21e-dmauger@cwe]; Gretchen LeMay [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ecac537a42344283ba12d9065b1b401e-Gretchen Le]; Erik Peterson [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a8a34be6a21849e0a396d416aed069e1-Erick Peter]; Ulises Rodela [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=13f3ff935c034511ad33438ce28b1179-urodela@cwe]; Mart Brosas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=61c8caf58b83438989eac3cede9fdc0c-Mart Brosas]; Tim Boyd [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fca1abc2e2a14cf7920bb81e8c259070-Tim Boyd]
CC: cwerks_salaried_associates [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb5f7fbf66e24ea6b93f183a438c8d0d-cwerks_sala]
Subject: RE: FDA Inspection Routine Inspection - Day 2
Attachments: MEMORANDUM OF OBSERVATION.pdf

Good day all,

Attached you will find Regulatory Observations made during the FDA inspection at Bartlett held 9.28-29.2022.

I am hopeful that this will help clarify the asks that were made and the findings noted from the inspection.

If you should have any questions comments or concerns, please feel free to reach out to me at your earliest convenience.

Everyone have an awesome weekend.

[[#]]
Name: Mary Madison
Phone: 773.297.9569

[[#]]

From: Erich Zicher <ezicher@cwerksglobal.com>
Sent: Thursday, September 29, 2022 9:38 PM
To: Anupam Sharma <asharma@cwerksglobal.com>; Angela Knabe <aknabe@cwerksglobal.com>; Mary Madison <mmadison@cwerksglobal.com>; Patrick Woodward <pwoodward@cwerksglobal.com>; Wendy Proulx <wproulx@cwerksglobal.com>; Billy King <bking@cwerksglobal.com>; Teresa Noles-Puccio <tnpuccio@cwerksglobal.com>; Ronald Sammeth <rsammeth@cwerksglobal.com>; Steve Schroeder <sschroeder@cwerksglobal.com>; Jürgen Peters <jpeters@cwerksglobal.com>; Doug Mauger <dmauger@cwerksglobal.com>; Gretchen LeMay <glemay@cwerksglobal.com>; Erik Peterson <epeterson@cwerksglobal.com>; Ulises Rodela <urodela@cwerksglobal.com>; Mart Brosas <Mbrosas@cwerksglobal.com>; Tim Boyd <tboyd@cwerksglobal.com>
Cc: cwerks_salaried_associates <cwerks_salaried_associates@cwerksglobal.com>
Subject: FDA Inspection Routine Inspection - Day 2

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1. Doc review: Pest control records demonstrated that our service provider needs to improve upon their communication
2. Doc review: Consistency of manual training records was mentioned pertaining to the printing/signing/dating of recipient names
3. Walk: Dock door #5 had light showing at the base of the door
4. Walk: EE cleaning LN 7300 was witnessed touching the floor and then using same hand to continue cleaning
5. Pepsi Complaint: Concern over lack of urgency in addressing the referenced FDA complaint (complaint received from PepsiCo: 5/28/21, CA completed by CW: 6/7/21, date of FDA referenced complaint: Oct. '21)

I would like to thank the Bartlett Leadership Team for their efforts in supporting this visit. The site showed extremely well, aside of the two observations noted by the inspector. I would also like to express my appreciation for @Anupam, @Angela, @Mary, @Patrick, @Wendy, @Teresa, @Billy, all whom supported various parts of the inspection and document review. Thanks also for @Ronald in being available for both escalations during the inspection and being able to join in at a moment's notice for the closeout meeting.

Me and my team will be reaching out to clients as required per their respective quality manuals to inform them of the visit. Please let me know should there be any questions.

Best,

creative werks

Erich Zicher
Director of Food Safety

1470 Brummel Ave,
Elk Grove Village, IL 60007
+1-630-509-3087 *(office)*
+1-847-826-9424 *(mobile)*
creative-werks.com

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

MARY MADISON,	)	
	)	
Plaintiff,	)	No. 23-cv-16476
v.	)	
	)	Hon. Manish S. Shah
CREATIVE WERKS LLC,	)	
and STEVE SCHROEDER, Individually	)	
	)	
Defendants.	)	
	)	

Exhibit 4

Message

From: Mary Madison [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=FB6C19E0FBC447F2BBA7F81A69088EB2-MARY MADISO]
Sent: 9/30/2022 7:53:23 PM
To: Erich Zicher [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8869b5871c2245a09d77cb6a5aa04269-Erich Ziche]; Anupam Sharma [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1a1f86487e5640f2b94906dcacb1b4db-Anupam Shar]; Angela Knabe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12e3c66a3f9240f49244dd2f43dc3f05-Angela Knab]; Patrick Woodward [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9af0c6cc0b624e1684367f5b66f4b683-pwoodward@c]; Wendy Proulx [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6be4922011dc41db8b28150dbfe97f0a-Wendy Proul]; Billy King [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e7ae719d39f7482cba50bfa24df873c3-Billy King]; Teresa Noles-Puccio [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbd110e96b97493fa14073727798a02d-tnpuccio@cw]; Ronald Sammeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d101e6ad5e1646b7a3e9658b45741cdb-Ronald Samm]; Steve Schroeder [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=576157045b2e4cfd8f668b80846d752d-sschroeder@]; Jürgen Peters [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7ffe8a4dd39045438bb5479f3f0cff6e-jpeters@cwe]; Doug Mauger [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f9c78d76045649d8a2d7dc6da299b21e-dmauger@cwe]; Gretchen LeMay [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ecac537a42344283ba12d9065b1b401e-Gretchen Le]; Erik Peterson [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a8a34be6a21849e0a396d416aed069e1-Erick Peter]; Ulises Rodela [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=13f3ff935c034511ad33438ce28b1179-urodela@cwe]; Mart Brosas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=61c8caf58b83438989eac3cede9fdc0c-Mart Brosas]; Tim Boyd [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fca1abc2e2a14cf7920bb81e8c259070-Tim Boyd]
CC: cwerks_salaried_associates [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb5f7fbf66e24ea6b93f183a438c8d0d-cwerks_sala]
Subject: RE: FDA Inspection Routine Inspection - Day 2
Attachments: MEMORANDUM OF OBSERVATION.pdf

Good day all,

Attached you will find Regulatory Observations made during the FDA inspection at Bartlett held 9.28-29.2022.

I am hopeful that this will help clarify the asks that were made and the findings noted from the inspection.

If you should have any questions comments or concerns, please feel free to reach out to me at your earliest convenience.

Everyone have an awesome weekend.

[[#]]
Name: Mary Madison
Phone: 773.297.9569

[[#]]

From: Erich Zicher <ezicher@cwerksglobal.com>
Sent: Thursday, September 29, 2022 9:38 PM
To: Anupam Sharma <asharma@cwerksglobal.com>; Angela Knabe <aknabe@cwerksglobal.com>; Mary Madison <mmadison@cwerksglobal.com>; Patrick Woodward <pwoodward@cwerksglobal.com>; Wendy Proulx <wproulx@cwerksglobal.com>; Billy King <bking@cwerksglobal.com>; Teresa Noles-Puccio <tnpuccio@cwerksglobal.com>; Ronald Sammeth <rsammeth@cwerksglobal.com>; Steve Schroeder <sschroeder@cwerksglobal.com>; Jürgen Peters <jpeters@cwerksglobal.com>; Doug Mauger <dmauger@cwerksglobal.com>; Gretchen LeMay <glemay@cwerksglobal.com>; Erik Peterson <epeterson@cwerksglobal.com>; Ulises Rodela <urodela@cwerksglobal.com>; Mart Brosas <Mbrosas@cwerksglobal.com>; Tim Boyd <tboyd@cwerksglobal.com>
Cc: cwerks_salaried_associates <cwerks_salaried_associates@cwerksglobal.com>
Subject: FDA Inspection Routine Inspection - Day 2

Hello Team,

We concluded our FDA inspection earlier this evening. High level summary of today's visit is as follows:

- Inspector arrived at 12:40 PM
- Rereviewed the complaint related to PepsiCo that was discussed yesterday
- Confirmed our refuse hauler information was consistent with Bru
- Review of Pest Control Records
- Review of Sanitary Transit Records
- Review of Food Safety Plan Process Flow Diagrams
- Review of Environmental Monitoring and Water Testing
- Review of Sanitation Processes
- Discussed Label Control
- Tour of Bartlett (Details in Closeout Meeting Observations)
- Inspector Reviewed Details of Packaging Sample Collected
- Inspector Performed Closeout Meeting (Details in Closeout Meeting Observations)
- Inspector concluded at approximately 6:25 PM

Closeout Meeting

Attendees:
- Ron Sammeth
- Erich Zicher
- Anu Sharma
- Mary Madison

Feedback: no 483's were issued for the visit. The below were discussion points that the inspector indicated will be included in the report:

1. Doc review: Pest control records demonstrated that our service provider needs to improve upon their communication
2. Doc review: Consistency of manual training records was mentioned pertaining to the printing/signing/dating of recipient names
3. Walk: Dock door #5 had light showing at the base of the door
4. Walk: EE cleaning LN 7300 was witnessed touching the floor and then using same hand to continue cleaning
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Me and my team will be reaching out to clients as required per their respective quality manuals to inform them of the visit. Please let me know should there be any questions.

Best,

creative werks

Erich Zicher
Director of Food Safety

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Elk Grove Village, IL 60007
+1-630-509-3087 *(office)*
+1-847-826-9424 *(mobile)*
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UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

MARY MADISON,	)	
	)	
Plaintiff,	)	No. 23-cv-16476
v.	)	
	)	Hon. Manish S. Shah
CREATIVE WERKS LLC,	)	
and STEVE SCHROEDER, Individually	)	
	)	
Defendants.	)	
	)	

Exhibit 5

SQF Food Safety Audit Edition 9

creative werks LLC - creative werks LLC

Summary

AUDIT DECISION
CERTIFIED

CERTIFICATION NUMBER
103278 | 154021

AUDIT RATING
96
Excellent

DECISION DATE
03/29/2022

AUDIT TYPE
RECERTIFICATION

RECERTIFICATION DATE
02/28/2023

AUDIT DATES
02/01/2022 - 02/03/2022

EXPIRATION DATE
05/14/2023

ISSUE DATE
03/29/2022

Facility & Scope

creative werks LLC (44756)
creative werks LLC
1470 Brummel Ave
Elk Grove Village, IL 60007
United States

Food Sector Categories:
25. Repackaging of Products Not Manufactured On Site
27. Manufacture of Food Packaging

Products:
(25) Confectionary, Snacks (27) Food-Grade Packaging Materials

Scope of Certification:
(25) Confectionary, Snacks (27) Food-Grade Packaging Materials

Certification Body & Audit Team

Mérieux NutriSciences Certification
401 N Michigan
Suite 1400
Chicago, IL 60611
United States

Web Site: https://www.merieuxnutrisciences.com/

CB#: CB-1-Mérieux
Accreditation Body: JAS-ANZ
Accreditation Number: Z3720906AB

Lead Auditor: Baker, Ute (9745)
Technical Reviewer: Lastra, Jaime (10049)

Hours Spent on Site: 23
Hours of ICT Activities: 0
Hours Spent Writing Report: 8

Non-Conforming

EXHIBIT
tabbies
#14
DA 3/24/25

2.4.3 Food Safety Plan (Mandatory)

There are four food safety plans in place for the repacking of Confectionary, Snacks, grinding of coffee and the production of Food-Grade Packaging Materials. The plans were developed using the FSMA requirements. The food safety plans have been implemented and include all products under the scope of certification. A multi-disciplinary team was used to develop the plans. The scope of each plan is from receiving to shipping. All inputs and outputs were documented. Product descriptions were in place. The product descriptions include the product type, food safety characteristics, customer/consumer use, Packaging types, Target market, distribution and storage control and shelf life. Flow diagrams are in place for each plan. The flow diagrams start at receiving and end at shipping. All inputs and outputs were documented including returned products and rework. A hazard analysis was completed for each step in the process. Biological hazards for the plans were identified as Salmonella, Aerobic Microbial, yeast and mold. Chemical hazards are identified as oil, lubricants, silicon, toluene (for food grade packaging), allergens, residual chemicals, oil, lubricants, sanitation chemicals, Heavy metals, Residual styrene monomers, sanitation chemicals, and allergens. Physical contaminates are identified as glass/BP, wood, and metal. Radiological hazards have been identified as the x-ray used in the process. The x-ray is not considered a radiological hazard. Process Preventative control has been identified for foreign material is Metal detection/x-ray - a working metal detector/x-ray that is checked every two hours. If the metal detector/x-ray does not work, product is placed on hold to the last good check. Product is run back through a working metal detector/x-ray. Allergen Preventative controls, sanitation preventative controls, and supply chain preventative controls are also in place. The packaging plan was reassessed on Apr. 6, 2021. There is one PPC in the plan. X-ray/metal detector. The manufacturing plan was reassessed on Apr. 6, 2021. There are no PPC's addressed in the plan. Minor - The Coffee plan has not been reviewed since Mar. 18, 2020. The Dunkeroos Plan was reassessed on Dec. 12, 2021. The PPC is identified as x-ray. The plans have been implemented and are part of the SQF verification.

2.4.3.14 The documented and approved food safety plan(s) shall be implemented in full. The effective implementation shall be monitored by the food safety team, and a full review of the documented and implemented plans shall be conducted at least annually, or when changes to the process, equipment, inputs, or other changes affecting product safety occur.

RESPONSE: MINOR

EVIDENCE: The Coffee plan has not been reviewed since Mar. 18, 2020.

ROOT CAUSE: Coffee Plan was not reviewed with the other Food Safety Plans

CORRECTIVE ACTION: Coffee Plan was reviewed and signed off.

VERIFICATION OF CLOSEOUT: Reviewed the plan and sign off. Approved the corrective action.

COMPLETION DATE: 02/22/2022 **CLOSEOUT DATE:** 02/24/2022

11.1.2 Building Materials

Floors were in overall good condition. Drains are located in the sanitation rooms in all facilities. There are no drains in production. The drains were in good condition. A risk analysis was conduct in May 2021 for all 3 facilities for ducting and piping along with wastewater pipes. The risk analysis showed the pipes were in good condition and did not pose a contamination risk. The piping was in good condition. Doors and windows were in good condition and of solid construction. Windows were constructed of shatterproof materials. Ceilings were in overall good condition. Platforms and stairs over production lines were in good condition and of solid construction.

11.1.2.4 Walls, partitions, ceilings, and doors shall be of durable construction. Internal surfaces shall have an even and regular surface and be impervious with a light-colored finish and shall be kept clean (refer to 11.2.5). Wall-to-wall and wall-to-floor junctions shall be designed to be easily cleaned and sealed to prevent the accumulation of food debris.

RESPONSE: MINOR

EVIDENCE: In the 50 and 70 line in Bentonville, there was a gap along the top of the perimeter of the interior wall.

ROOT CAUSE: No one had identified there was a gap at the top of the interior perimeter wall.

CORRECTIVE ACTION: Gap was closed on the interior perimeter wall

VERIFICATION OF CLOSEOUT: Reviewed the picture and approved the corrective action.

COMPLETION DATE: 02/21/2022 **CLOSEOUT DATE:** 02/24/2022

11.4.1 Staff Engaged in Food Handling and Processing Operations

Employees were observed entering the processing areas through the proper doorways. Doors were closed. Ingredients and products were stored off of the floor. Employees were observed following proper GMP's. Minor - Several candy wrappers were observed in the yellow pole protectors in the warehouse area at the Elk Grove facility. The flow of employees is from open components to packaged product. No contamination issues were observed. Sensory evaluations are conducted in the kitchen area.

11.4.1.2 Personnel working in or visiting food handling or processing operations shall ensure that: i. Staff shall not eat or taste any product being processed in the food handling/contact zones, except as noted in element 11.4.1.4; ii. The wearing of false fingernails, false eyelashes, eyelash extensions, long nails, or fingernail polish is not permitted when handling exposed food; iii. Hair restraints and beard covers, where applicable, shall be used in areas where product is exposed. iv. Smoking, chewing, eating, or spitting is not permitted in areas where product is produced, stored, or otherwise exposed. v. Drinking water is permissible only under conditions that prevent contamination or other food safety risks from occurring. Drinking water containers in production and storage areas shall be stored in clear, covered containers, and in designated areas away from raw materials, packaging, tools, or equipment storage.

RESPONSE: MINOR

EVIDENCE: Several candy wrappers were observed in the yellow pole protectors in the warehouse area at the Elk Grove facility.

ROOT CAUSE: Employees are trained upon hire that no eating is to be done in non-designated areas. Warehouse personnel needed to be reminded of proceudre.

CORRECTIVE ACTION: Candy wrappers were removed during the audit. Warehouse personnal received a re-training about posted GMPs and that eating can only be done designated areas.

VERIFICATION OF CLOSEOUT: Reviewed the training record and approved the corrective action.

COMPLETION DATE: 02/16/2022 **CLOSEOUT DATE:** 02/24/2022

13.1.5 Ventilation

There was an adequate amount of ventilation in the facility. Minor - Several fans by the lines in the blow molding area (Bartlett) had dust build up.

13.1.5.1 Adequate ventilation shall be provided in enclosed packaging manufacture and handling areas.

RESPONSE: MINOR

EVIDENCE: Several fans by the lines in the blow molding area (Bartlett) had dust build up.

ROOT CAUSE: Fans were not included in the weekly cleaning checklist.

CORRECTIVE ACTION: Fans were added to the weekly cleaning checklist for Blow Molding and Winding

VERIFICATION OF CLOSEOUT: Reviewed the new MS schedule and approved the corrective action.

COMPLETION DATE: 02/18/2022 **CLOSEOUT DATE:** 02/24/2024

Audit Statements

SQF Practitioner Name	Name the designated SQF Practitioner **RESPONSE:** Angela Knabe
SQF Practitioner Email	Email of the designated SQF Practitioner **RESPONSE:** aknabe@cwerksglobal.com
Opening Meeting	People Present at the Opening Meeting (Please list names and roles in the following format Name: Role separated by commas) **RESPONSE:** Erich Zicher: Director of Food Safety, Angela Knabe: Quality Regulatory Manager, Matt Burke: QA Manager (Brummel), Ute Baker: Auditor.
Facility Description	Auditor Description of Facility (Please provide facility description include # of employees, size, production schedule, general layout, and any additional pertinent details **RESPONSE:** CreativeWerks is located in three locations. The locations are Elk Grove Village, Bensenville and Bartlett. Elk Grove Village is approximately 250,000 sq ft. consisting of dry storage, 10 bagger lines, one coffee repack room, docks, employee welfare areas and offices. The Bartlett facility is 400.000 sq ft. consisting of a two primary packaging manufacturing rooms - topper making lines and winding packaging. The site also has two packaging rooms for repacking of products along with dry storage, employee welfare areas, dock areas and office areas. The Bensenville facility is approximately 180,000 sq ft. consisting of a separate area for allergen packing, dry storage, repacking lines, dock areas and office. The company employees approximately 150 employees during the slow season and up to 1000 during the busy season. The employees work 3 eight hour shifts five to six days per week. Dry sanitation is conducted during the week and deep sanitation is conducted on a defined schedule depending on the line. The facility produces primary packaging and repackages confectionary and snacks under SQF codes 27 and 25 for customers.
Closing Meeting	People Present at the Closing Meeting (Please list names and roles in the following format Name: Role separated by commas) **RESPONSE:** Erich Zicher: Director of Food Safety, Angie Knabe: Quality Regulatory Manager, Michaela Keslerova: Food Safety Quality Manager - Bensenville, Matthew Burke: Food Safety Quality Manager – Elk Grove Village, Steve Schroeder: President, Jurgen Peters: EVP of Sales and Marketing, Patrick Woodard: Vice President and Chief Financial Officer, Ronald Sammeth: Chief Operating Officer, Anu Sharma: Food Safety Quality Manager – Bartlett, Doug Mauger: Vice President of Manufacturing and Engineering, Ute Baker: Auditor
Auditor Recommendation	Auditor Recommendation **RESPONSE:** Recertify

Section Responses

2.1.1 Management Responsibility (Mandatory)

A Food Safety Policy/Statement is in place. The policy statement was signed by the Director of Quality, VP of Manufacturing and Engineering and the Senior Director of Client Services on Sept. 23, 2021. The policy statement includes the company's commitment to supply safe products that meet customer and regulatory requirements. Food safety objectives are reviewed annually. The policy was posted at the employee entrances in English and Spanish at all three facilities. A Food Safety policy is in place. Employees are trained at time of hire and refresher training is conducted at annually. Employees are allowed to mitigate issues or stop the line. The site has implemented a see something say something policy with employees. Daily employee huddles are conducted with employees. Employees are encouraged to say if there are any issues. An organizational chart is in place. The chart shows the employees responsible for food safety. The chart was updated Dec. 2021. Job descriptions are in place. The job descriptions include who covers whom in case of absences. The Quality Regulatory Manager is the SQF Practitioner at the sites. She was HACCP trained Jan. 21 - 22, 2013. She also completed PCQI training on Jun. 30, 2017. The Director of Food Safety is the back up Practitioner. He was PCQI trained on Sept. 15, 2016 and HACCP trained on Sept. 23, 2015. Both showed knowledge in SQF and HACCP. Training is completed at time of hire and annually. Job specific training is completed. The sites ensure continuous operations in case of personnel changes with the back up positions that are in place. The site is aware of the blackout policy for the unannounced audits.

2.1.1.1 Senior site management shall prepare and implement a policy statement that outlines at a minimum the commitment of all site management to: i. Supply safe food; ii.Establish and maintain a food safety culture within the site; iii. Establish and continually improve the site's food safety management system; and iv. Comply with customer and regulatory requirements to supply safe food. The policy statement shall be: v. Signed by the senior site manager and displayed in prominent positions; and vi. Effectively communicated to all site personnel in the language(s) understood by all site personnel.

RESPONSE: COMPLIANT

2.1.1.2 Senior site management shall lead and support a food safety culture within the site that ensures at a minimum: i. The establishment, documentation, and communication to all relevant staff of food safety objectives and performance measures; ii. Adequate resources are available to meet food safety objectives; iii. Food safety practices and all applicable requirements of the SQF System are adopted and maintained; iv. Employees are informed and held accountable for their food safety and regulatory responsibilities; v. Employees are positively encouraged and required to notify management about actual or potential food safety issues; and vi. Employees are empowered to act to resolve food safety issues within their scope of work.

RESPONSE: COMPLIANT

2.1.1.3 The reporting structure shall identify and describe site personnel with specific responsibilities for tasks within the food safety management system and identify a backup for the absence of key personnel. Job descriptions for the key personnel shall be documented. Site management shall ensure departments and operations are appropriately staffed and organizationally aligned to meet food safety objectives.

RESPONSE: COMPLIANT

2.1.1.4 Senior site management shall designate a primary and substitute SQF practitioner for each site with responsibility and authority to: i. Oversee the development, implementation, review, and maintenance of the SQF System; ii. Take appropriate action to ensure the integrity of the SQF System; and iii. Communicate to relevant personnel all information essential to ensure the effective implementation and maintenance of the SQF System.

RESPONSE: COMPLIANT

2.1.1.5 The primary and substitute SQF practitioner shall: i. Be employed by the site; ii. Hold a position of responsibility related to the management of the site's SQF System; iii. Have completed a HACCP training course; iv. Be competent to implement and maintain HACCP based food safety plans; and v. Have an understanding of the SQF Food Safety Code: Food Manufacturing and the requirements to implement and maintain an SQF System relevant to the site's scope of certification

RESPONSE: COMPLIANT

2.1.1.6 Senior site management shall ensure the training needs of the site are resourced, implemented, and meet the requirements outlined in system elements 2.9 and that site personnel meet the required competencies to carry out those functions affecting the legality and safety of food products.

RESPONSE: COMPLIANT

2.1.1.7 Senior site management shall ensure the integrity and continued operation of the food safety system in the event of organizational or personnel changes within the company or associated facilities.

RESPONSE: COMPLIANT

2.1.1.8 Senior site management shall designate defined blackout periods that prevent unannounced re-certification audits from occurring out of season or when the site is not operating for legitimate business reasons. The list of blackout dates and their justification shall be submitted to the certification body a minimum of one (1) month before the sixty (60) day re-certification window for the agreed-upon unannounced audit.

RESPONSE: COMPLIANT

2.1.2 Management Review (Mandatory)

A management review was conducted on Jan. 19, 2022. The policy manual was reviewed on Mar. 5, 2021. Internal and external audit results were reviewed along with the corrective actions. Trends in customer complaints were reviewed along with resolutions. Monthly meetings are conducted to review any issues that have occurred during the month. The SQF system was reviewed in its entirety. The Food Safety plans, GMP's, and pre-requisite programs are reviewed when changes are made to the system. Records for monthly meetings were reviewed for Jan. 19, 2022, Dec. 8, 2021 and Nov. 10, 2021. All records were complete.

2.1.2.1 The SQF System shall be reviewed by senior site management at least annually and include: i. Changes to food safety management system documentation (policies, procedures, specifications, food safety plan); ii. Food safety culture performance; iii. Food safety objectives and performance measures; iv. Corrective and preventative actions and trends in findings from internal and external audits, customer complaints, and verification and validation activities; v. Hazard and risk management system; and vi. Follow-up action items from previous management reviews. Records of all management reviews and updates shall be maintained.

RESPONSE: COMPLIANT

2.1.2.2 The SQF practitioner(s) shall update senior site management on at least a monthly basis on matters impacting the implementation and maintenance of the SQF System. The updates and management responses shall be documented.

RESPONSE: COMPLIANT

2.1.3 Complaint Management (Mandatory)

A Customer Complain policy is in place. The policy was updated on May 21, 2019. Complaints are received by Sales and Marketing, Client Services or Quality Assurance. The complaints are reviewed and are investigated as needed. Trends of complaints are maintained. The main food safety complaint for the year was for foreign material. Investigations were conducted. Root cause analysis was completed and corrective actions were implemented. Records for complaints were maintained along with the investigations. Records reviewed for Nov. thru Jan. 2022 were complete.

2.1.3.1 The methods and responsibility for handling, investigating, and resolving food safety complaints from commercial customers, consumers, and authorities, arising from products manufactured or handled on-site or co-manufactured, shall be documented and implemented.

RESPONSE: COMPLIANT

2.1.3.2 Adverse trends of customer complaint data shall be investigated and analyzed and the root cause established by personnel knowledgeable about the incidents.

RESPONSE: COMPLIANT

2.1.3.3 Corrective and preventative action shall be implemented based on the seriousness of the incident and the root cause analysis as outlined in 2.5.3. Records of customer complaints, their investigation, and resolution shall be maintained.

RESPONSE: COMPLIANT

2.2.1 Food Safety Management System (Mandatory)

A food safety management system is in place. The manual is maintained electronically. The manual includes the food safety policies, the policy statement, organizational chart, scope of certification and products covered under the scope of certification. Pre-requisite programs and the food safety plans are also included. Any changes to the food safety plans, GMP's and pre-requisite programs will be validated or justified.

2.2.1.1 The methods and procedures the site uses to meet the requirements of the SQF Food Safety Code: Food Manufacturing shall be maintained in electronic and/or hard copy documentation. They will be made available to relevant staff and include: i. A summary of the organization's food safety policies and the methods it will apply to meet the requirements of this standard; ii. The food safety policy statement and organization chart; iii. The processes and products included in the scope of certification; iv. Food safety regulations that apply to the manufacturing site and the country(ies) of sale (if known); v. Raw material, ingredient, packaging, and finished product specifications; vi. Food safety procedures, prerequisite programs, food safety plans; vii. Process controls that impact product safety; and viii. Other documentation necessary to support the development, implementation, maintenance, and control of the SQF System.

RESPONSE: COMPLIANT

2.2.1.2 Food safety plans, Good Manufacturing Practices, and all relevant aspects of the SQF System shall be reviewed, updated, and communicated as needed when any changes implemented have an impact on the site's ability to deliver safe food. All changes to food safety plans, Good Manufacturing Practices, and other aspects of the SQF System shall be validated or justified prior to their implementation. The reasons for the change shall be documented.

RESPONSE: COMPLIANT

2.2.2 Document Control (Mandatory)

A Document Control Policy is in place. The policy was updated on Sept. 8, 2020. The policy has been implemented. The Director of Quality is responsible for maintaining the program. All revisions are approved by the Director of Quality and updated in the register. A register of SQF System documents is maintained. The register was updated on Feb. 1, 2022. All documents were safely stored and readily accessible.

2.2.2.1 The methods and responsibility for maintaining document control and ensuring staff have access to current requirements and instructions shall be documented and implemented. Current SQF System documents and amendments to documents shall be maintained.

RESPONSE: COMPLIANT

2.2.3 Records (Mandatory)

How records are to be maintained is part of the document control policy. Records are maintained per regulatory and customer requirements. Records were reviewed for bags per case, temper proof, odor test, appearance, gusset check, zipper check, tear notch, correct allergen, code date for case and package, weights, seal, product damage, verify material, and metal detection. Records were reviewed for Jan. 11 - 13, Apr. 13 - 15, Jul. 14 - 16, and Nov. 16 - 18, 2021. The records were complete, verified and legible.

2.2.3.1 The methods, frequency, and responsibility for verifying, maintaining, and retaining records shall be documented and implemented.

RESPONSE: COMPLIANT

2.2.3.2 All records shall be legible and confirmed by those undertaking monitoring activities that demonstrate inspections, analyses, and other essential activities that have been completed.

RESPONSE: COMPLIANT

2.2.3.3 Records shall be readily accessible, retrievable, and securely stored to prevent unauthorized access, loss, damage, and deterioration. Retention periods shall be in accordance with customer, legal, and regulatory requirements, at minimum the product shelf-life or established by the site if no shelf-life exists.

RESPONSE: COMPLIANT

2.3.1 Specification, Formulation and Realization

Product design for the packaging materials is between the customer and the work shop design group. Food products are from the customer. New product formulations are verified and validated with plant trials. The customer is responsible for supplying the best by dates, microbiological criteria, storage and handling requirements. The food safety plans will be validated and verified for new products and processes. The food safety plans will be reviewed when changes are made to products or materials. The process flow for new products will be designed not to cross contaminate product. Records for the new Dunkaroo line were reviewed for the production line going back to Jan. 2021. The line was started on Dec. 20, 2021. Records for all approvals were in place and complete. Labels were approved by the customer and reviewed by the site.

2.3.1.1 The methods and responsibility for designing and developing new product formulations and converting product concepts to commercial realization shall be documented and implemented.

RESPONSE: COMPLIANT

2.3.1.2 New product formulations, manufacturing processes, and the fulfillment of product requirements shall be established, validated, and verified by site trials and product testing as required to ensure product safety. Product formulations shall be developed by authorized persons to ensure that they meet the intended use. Where necessary, shelf life trials shall be conducted to validate and verify a new product's: i. Pre-consumer handling and storage requirements, including the establishment of "use by," "best before dates," or equivalent terminology; ii. Microbiological criteria, where applicable; and iii. Consumer preparation, where applicable, and storage and handling requirements.

RESPONSE: COMPLIANT

2.3.1.3 A food safety plan shall be validated and verified by the site food safety team for each new product and its associated process through conversion to commercial production and distribution or where a change to ingredients, process, or packaging occurs that may impact food safety.

RESPONSE: COMPLIANT

2.3.1.4 Product formulations and manufacturing processes for products included in the scope of certification shall be reviewed when there are changes in materials, ingredients, or equipment.

RESPONSE: COMPLIANT

2.3.1.5 The process flows for all new and existing manufacturing processes shall be designed to ensure that product is manufactured according to approved product formulations and to prevent cross-contamination.

RESPONSE: COMPLIANT

2.3.1.6 Records of product design, formulations, label compliance, process flows, shelf life trials, and approvals for all new and existing products shall be maintained.

RESPONSE: COMPLIANT

2.3.2 Specifications (Raw Material, Packaging, Finished Product and Services)

Specifications are in place for components, packaging materials and resin. The resin, packaging materials and components received complied with relevant legislation. Specifications for components and how they are to be assembled are received from the customers. Resin and packaging material specifications are developed between the technical services manager, supplier and procurement. Materials received from other sites must comply with specifications. Components are validated with certificates of analysis. Packaging materials and resin are validated with letters of guarantee. The customer and suppliers are required to notify the company if there are changes to the component or ingredient. Packaging materials and resin are validated with letters of guarantee. A letter of guarantee was reviewed for Resin dated Jan. 9, 2019. Finished product labels reviewed were accurate and complied with relevant legislation. The labels are approved by the customer and reviewed by the facility at time of use. Specifications are in place for service providers. The specifications include the service that is to be provided. A register of service providers is in place and was current for the vending machine, outside laboratory, uniforms and pest control. The register was updated on Nov. 15, 2021. Finished product specifications are maintained in SharePoint. The finished product specifications include the weight requirements, code date requirements, labeling and packaging requirements. Microbiological and chemical requirements are based on customer requirements and are sent to a third party laboratory. A register of finished product specifications and labels are maintained and were current.

2.3.2.1 The methods and responsibility for developing, managing, and approving raw material, finished product, and packaging specifications shall be documented.

RESPONSE: COMPLIANT

2.3.2.2 Specifications for all raw materials and packaging, including, but not limited to, ingredients, additives, hazardous chemicals, processing aids, and packaging that impact finished product safety shall be documented and kept current.

RESPONSE: COMPLIANT

2.3.2.3 All raw materials, packaging, and ingredients, including those received from other sites under the same corporate ownership, shall comply with specifications and with the relevant legislation in the country of manufacture and country(ies) of destination if known.

RESPONSE: COMPLIANT

2.3.2.4 Raw materials, packaging, and ingredients shall be validated to ensure product safety is not compromised and the material is fit for its intended purpose.

RESPONSE: COMPLIANT

2.3.2.5 Site management shall require approved raw materials suppliers to notify the site of changes in product composition that could have an impact on product formulation (e.g., protein content, moisture, amino acid profiles, contaminant levels, allergens, and/or other parameters that may vary by crop or by season).

RESPONSE: COMPLIANT

2.3.2.6 Verification of packaging shall include a certification of all packaging that comes into direct contact with food meets either regulatory acceptance or approval criteria. Documentation shall either be in the form of a declaration of continued guarantee of compliance, a certificate of conformance, or a certificate from the applicable regulatory agency. In the absence of a certificate of conformance, certificate of analysis, or letter of guarantee, analyses to confirm the absence of potential chemical migration from the packaging to the food contents shall be conducted and records maintained.

RESPONSE: COMPLIANT

2.3.2.7 Finished product labels shall be accurate, comply with the relevant legislation, and be approved by qualified company personnel.

RESPONSE: COMPLIANT

2.3.2.8 Description of services for contract service providers that have an impact on product safety shall be documented, current, include a full description of the services to be provided, and detail relevant training requirements of all contract personnel.

RESPONSE: COMPLIANT

2.3.2.9 Finished product specifications shall be documented, current, approved by the site and its customer, accessible to relevant staff, and shall include, where applicable: i. Microbiological, chemical, and physical limits; ii. Composition to meet label claims; iii. Labeling and packaging requirements; and iv. Storage conditions.

RESPONSE: COMPLIANT

2.3.2.10 Specifications for raw materials and packaging, chemicals, processing aids, contract services, and finished products shall be reviewed as changes occur that impact product safety. Records of reviews shall be maintained. A list of all the above specifications shall be maintained and kept current.

RESPONSE: COMPLIANT

2.3.3 Contract Manufacturers

Contract Manufactures are not used.

2.3.3.1 The methods and responsibility for ensuring all agreements with contract manufacturers relating to food safety, customer product requirements, their realization, and delivery shall be documented and implemented.

RESPONSE: NOT APPLICABLE

2.3.3.2 The site shall establish a method to determine the food safety risk level of contract manufactured product and shall document the risk. The site shall ensure that: i. Products and processes of co-manufacturers that are considered high-risk have undergone an audit by the site or third-party agency to confirm compliance with the SQF Food Safety Code: Food Manufacturing and regulatory and customer requirements; ii. Products and processes of co-manufacturers that are considered low-risk meet the requirements of the SQF Food Safety Code: Food Manufacturing, or other GFSI benchmarked certification programs, and regulatory and customer requirements; and iii. Changes to contractual agreements are approved by both parties and communicated to relevant personnel.

RESPONSE: NOT APPLICABLE

2.3.3.3 Contractual agreements with third party storage and distribution businesses shall include requirements relating to customer product requirements and compliance with clause 2.3.3.2 of the SQF Food Safety Code: Food Manufacturing. Contractual agreements shall be approved by both parties and communicated to relevant personnel. The site shall verify compliance with the SQF Code and ensure that customer and regulatory requirements are being met at all times.

RESPONSE: NOT APPLICABLE

2.3.3.4 Records of audits, contracts, and changes to contractual agreements and their approvals shall be maintained.

RESPONSE: NOT APPLICABLE

2.3.4 Approved Supplier Program (Mandatory)

A Supplier Approval Program is in place. The program was revised on Apr. 5, 2019. Procurement finds the suppliers. The Quality Regulatory Manager is responsible for approving the suppliers. A register of suppliers is in place. The register includes the suppliers contact information. Suppliers are required to provide a third party audit, specifications, food safety plan and other specified requirements. Verification of materials is with COA's and COC's. Unapproved suppliers are flagged in the system. The ingredient cannot be received. Ingredients and components received from other sites must be on the approved supplier list. Supplier audits are not conducted at this time.

2.3.4.1 The responsibility and procedure for selecting, evaluating, approving, and monitoring an approved supplier shall be documented and implemented. A current record of approved suppliers, receiving inspections, and supplier audits shall be maintained. Code Amendment #2 Approved supplier registers shall include supplier contact details. All approved and emergency suppliers shall be registered.

RESPONSE: COMPLIANT

2.3.4.2 The approved supplier program shall be based on the past performance of a supplier and the risk level of the raw materials, ingredients, processing aids, packaging, and services supplied, and shall contain at a minimum: i. Agreed specifications (refer to 2.3.2); ii. Reference to the level of risk applied to raw materials, ingredients, packaging, and services from the approved supplier; iii. A summary of the food safety controls implemented by the approved supplier; iv. Methods for granting approved supplier status; v. Methods and frequency of monitoring approved suppliers; vi. Details of the certificates of conformance, if required; and vii. Methods and frequency of reviewing approved supplier performance and status.

RESPONSE: COMPLIANT

2.3.4.3 Verification of raw materials shall include certificates of conformance, certificates of analysis, or sampling, and testing. The verification frequency shall be identified by the site.

RESPONSE: COMPLIANT

2.3.4.4 The receipt of raw materials, ingredients, processing aids, and packaging from nonapproved suppliers shall be acceptable only in an emergency situation and provided a receiving inspection or analysis is conducted and recorded before use.

RESPONSE: COMPLIANT

2.3.4.5 Raw materials, ingredients, and packaging received from other sites under the same corporate ownership shall be subject to the same specification requirements (refer to 2.3.2), approved supplier requirements, and receiving inspections as all other material providers.

RESPONSE: COMPLIANT

2.3.4.6 Supplier audits shall be based on risk (as determined in 2.3.4.2) and shall be conducted by individuals knowledgeable of applicable regulatory and food safety requirements and trained in auditing techniques.

RESPONSE: COMPLIANT

2.4.1 Food Legislation (Mandatory)

The site ensures, that at the time of delivery to the customers, the products supplied meet regulatory requirements. The labels reviewed included the net weights, product description, nutritional labeling, allergens, and were applicable labeling for organic, Halal, Kosher and non-GMO. The site stays informed of changes to legislation from customers, FDA website and e-mails, and scientific magazines. SQFI and the CB will be notified in writing within 24 hrs of a regulatory warning.

2.4.1.1 The site shall ensure that at the time of delivery to customers finished products shall comply with food safety legislation applicable in the country of manufacture and sale. This includes compliance with legislative requirements applicable to maximum residue limits, food safety, packaging, product description, net weights, nutritional, allergen, and additive labeling, labeling of identity preserved foods, any other criteria listed under food legislation, and to relevant established industry codes of practice.

RESPONSE: COMPLIANT

2.4.1.2 The methods and responsibility for ensuring the site is kept informed of changes to relevant legislation, scientific and technical developments, emerging food safety issues, and relevant industry codes of practice shall be documented and implemented.

RESPONSE: COMPLIANT

2.4.1.3 SQFI and the certification body shall be notified in writing within twenty-four (24) hours as a result of a regulatory warning or event. Notification to SQFI shall be by email to foodsafetycrisis@sqfi.com.

RESPONSE: COMPLIANT

2.4.2 Good Manufacturing Practices (Mandatory)

The site has ensured that the Good Manufacturing Practices described in modules 11 and 13 of the Food Safety Code have been applied. There are no exemptions in place. The GMP's applicable to the scope of certification are documented and implemented.

2.4.2.1 The site shall ensure the applicable Good Manufacturing Practices described in Module 11 of this Food Safety Code are applied or exempted according to a written risk analysis outlining the justification for exemption or evidence of the effectiveness of alternative control measures that ensure food safety is not compromised.

RESPONSE: COMPLIANT

2.4.2.2 The Good Manufacturing Practices applicable to the scope of certification outlining how food safety is controlled and assured shall be documented and implemented.

RESPONSE: COMPLIANT

2.4.3 Food Safety Plan (Mandatory)

There are four food safety plans in place for the repacking of Confectionary, Snacks, grinding of coffee and the production of Food-Grade Packaging Materials. The plans were developed using the FSMA requirements. The food safety plans have been implemented and include all products under the scope of certification. A multi-disciplinary team was used to develop the plans. The scope of each plan is from receiving to shipping. All inputs and outputs were documented. Product descriptions were in place. The product descriptions include the product type, food safety characteristics, customer/consumer use, Packaging types, Target market, distribution and storage control and shelf life. Flow diagrams are in place for each plan. The flow diagrams start at receiving and end at shipping. All inputs and outputs were documented including returned products and rework. A hazard analysis was completed for each step in the process. Biological hazards for the plans were identified as Salmonella, Aerobic Microbial, yeast and mold. Chemical hazards are identified as oil, lubricants, silicon, toluene (for food grade packaging), allergens, residual chemicals, oil, lubricants, sanitation chemicals, Heavy metals, Residual styrene monomers, sanitation chemicals, and allergens. Physical contaminates are identified as glass/BP, wood, and metal. Radiological hazards have been identified as the x-ray used in the process. The x-ray is not considered a radiological hazard. Process Preventative control has been identified for foreign material is Metal detection/x-ray - a working metal detector/x-ray that is checked every two hours. If the metal detector/x-ray does not work, product is placed on hold to the last good check. Product is run back through a working metal detector/x-ray. Allergen Preventative controls, sanitation preventative controls, and supply chain preventative controls are also in place. The packaging plan was reassessed on Apr. 6, 2021. There is one PPC in the plan. X-ray/metal detector. The manufacturing plan was reassessed on Apr. 6, 2021. There are no PPC's addressed in the plan. Minor - The Coffee plan has not been reviewed since Mar. 18, 2020. The Dunkeroos Plan was reassessed on Dec. 12, 2021. The PPC is identified as x-ray. The plans have been implemented and are part of the SQF verification.

2.4.3.1 A food safety plan shall be prepared in accordance with the twelve steps identified in the Codex Alimentarius Commission HACCP guidelines. The food safety plan shall be effectively implemented and maintained and shall outline how the site controls and assures food safety of the products or product groups included in the scope of the SQF certification and their associated processes. More than one HACCP food safety plan may be required to cover all products included in the scope of certification.

RESPONSE: COMPLIANT

2.4.3.2 The food safety plan or plans shall be developed and maintained by a multidisciplinary team that includes the SQF practitioner and those site personnel with technical, production, and engineering knowledge of the relevant raw materials, packaging, processing aids, products, and associated processes. Where the relevant expertise is not available on-site, advice may be obtained from other sources to assist the food safety team.

RESPONSE: COMPLIANT

2.4.3.3 The scope of each food safety plan shall be developed and documented including the start and endpoints of the processes under consideration and all relevant inputs and outputs.

RESPONSE: COMPLIANT

2.4.3.4 Product descriptions shall be developed and documented for all products included in the scope of the food safety plans. The descriptions shall reference the finished product specifications (refer to 2.3.2.9) plus any additional information relevant to product safety, such as pH, water activity, composition, and/or storage conditions.

RESPONSE: COMPLIANT

2.4.3.5 The intended use of each product shall be determined and documented by the food safety team. This shall include target consumer groups, the potential for consumption by vulnerable groups of the population, requirements for further processing if applicable, and potential alternative uses of the product.

RESPONSE: COMPLIANT

2.4.3.6 The food safety team shall develop and document a flow diagram covering the scope of each food safety plan The flow diagram shall include every step in the process, all raw materials, packaging, service inputs (e.g., water, steam, gasses as applicable), scheduled process delays, and all process outputs including waste and rework. Each flow diagram shall be confirmed by the food safety team to cover all stages and hours of operation.

RESPONSE: COMPLIANT

2.4.3.7 The food safety team shall identify and document all food safety hazards that can reasonably be expected to occur at each step in the processes, including raw materials and other inputs.

RESPONSE: COMPLIANT

2.4.3.8 The food safety team shall conduct a hazard analysis for every identified hazard to determine which hazards are significant, i.e., their elimination or reduction to an acceptable level is necessary to control food safety. The methodology for determining hazard significance shall be documented and used consistently to assess all potential hazards.

RESPONSE: COMPLIANT

2.4.3.9 The food safety team shall determine and document the control measures that must be applied to all significant hazards. More than one control measure may be required to control an identified hazard, and more than one significant hazard may be controlled by a specific control measure.

RESPONSE: COMPLIANT

2.4.3.10 Based on the results of the hazard analysis (refer to 2.4.3.8), the food safety team shall identify the steps in the process where control must be applied to eliminate a significant hazard or reduce it to an acceptable level (i.e., a critical control point or CCP). In instances where a significant hazard has been identified at a step in the process, but no control measure exists, the food safety team shall modify the process to include an appropriate control measure.

RESPONSE: COMPLIANT

2.4.3.11 For each identified CCP, the food safety team shall identify and document the limits that separate safe from unsafe product (critical limits). The food safety team shall validate all of the critical limits to ensure the level of control of the identified food safety hazard(s) and that all critical limits and control measures individually or in combination effectively provide the level of control required (refer to 2.5.2.1).

RESPONSE: COMPLIANT

2.4.3.12 The food safety team shall develop and document procedures to monitor CCPs to ensure they remain within the established limits (refer to 2.4.3.11). Monitoring procedures shall identify the personnel assigned to conduct monitoring, the sampling and test methods, and the test frequency.

RESPONSE: COMPLIANT

2.4.3.13 The food safety team shall develop and document deviation procedures that identify the disposition of affected product when monitoring indicates a loss of control at a CCP. The procedures shall also prescribe actions to correct the process step to prevent recurrence of the safety failure.

RESPONSE: COMPLIANT

2.4.3.14 The documented and approved food safety plan(s) shall be implemented in full. The effective implementation shall be monitored by the food safety team, and a full review of the documented and implemented plans shall be conducted at least annually, or when changes to the process, equipment, inputs, or other changes affecting product safety occur.

RESPONSE: MINOR

EVIDENCE: The Coffee plan has not been reviewed since Mar. 18, 2020.

ROOT CAUSE: Coffee Plan was not reviewed with the other Food Safety Plans

CORRECTIVE ACTION: Coffee Plan was reviewed and signed off.

VERIFICATION OF CLOSEOUT: Reviewed the plan and sign off. Approved the corrective action.

COMPLETION DATE: 02/22/2022 **CLOSEOUT DATE:** 02/24/2022

2.4.3.15 Procedures shall be in place to verify that critical control points are effectively monitored and appropriate corrective actions are applied. Implemented food safety plans shall be verified as part of SQF System verification (refer to 2.5).

RESPONSE: COMPLIANT

2.4.3.16 Critical control point monitoring, corrective action, and verification records shall be maintained and appropriately used.

RESPONSE: COMPLIANT

2.4.3.17 Where food safety regulations in the country of production and destination (if known) prescribe a food safety control methodology other than the Codex Alimentarius Commission HACCP guidelines, the food safety team shall implement food safety plans that meet both Codex and food regulatory requirements.

RESPONSE: COMPLIANT

2.4.4 Product Sampling, Inspection and Analysis

The QA department is responsible for the inspection of products. Methods are in place on how the inspections are to be conducted. Checks are documented in Qwerks. Checks are conducted a minimum of every two hours for labels, weights, code dates, metal detection/x-ray, bag size, density, piece count, odor, appearance, and oxygen. Tubes and toppers are checked for appearance and fit. The sites do not have a laboratory. The external laboratory used is ISO 17025 certified. The certification expires on Mar. 31, 2022. Retention samples are maintained. The samples are maintained for five years. Records for inspections were reviewed for Jan. 11 - 13, Apr. 13 - 15, Jul. 14 - 16, and Nov. 16 - 18, 2021. The records were complete and verified.

2.4.4.1 The methods, responsibility, and criteria for sampling, inspecting, and/or analyzing raw materials, work-in-progress, and finished product shall be documented and implemented. The methods applied shall ensure that inspections and analyses are completed at regular intervals as required and to agreed specifications and legal requirements. Sampling and testing shall be representative of the process batch and ensure that process controls are maintained to meet specification and formulation.

RESPONSE: COMPLIANT

2.4.4.2 Product analyses shall be conducted to nationally recognized methods or company requirements, or alternative methods that are validated as equivalent to the nationally recognized methods. Where internal laboratories are used to conduct input, environmental, or product analyses, sampling and testing methods shall be in accordance with the applicable requirements of ISO/IEC 17025, including annual proficiency testing for staff conducting analyses. External laboratories shall be accredited to ISO/IEC 17025, or an equivalent international standard, and included on the site's contract service specifications list (refer to 2.3.2.11).

RESPONSE: COMPLIANT

2.4.4.3 On-site laboratories conducting chemical and microbiological analyses that may pose a risk to product safety shall be located separate from any food processing or handling activity and designed to limit access only to authorized personnel. Signage shall be displayed identifying the laboratory area as a restricted area, accessible only by authorized personnel.

RESPONSE: NOT APPLICABLE

EVIDENCE: The sites do not have laboratories.

2.4.4.4 Provisions shall be made to isolate and contain all hazardous laboratory waste held on the premises and manage it separately from food waste. Laboratory waste outlets shall at a minimum be downstream of drains that service food processing and handling areas.

RESPONSE: NOT APPLICABLE

EVIDENCE: The sites do not have laboratories.

2.4.4.5 Retention samples, if required by customers or regulations, shall be stored according to the typical storage conditions for the product and maintained for the stated shelflife of the product.

RESPONSE: COMPLIANT

2.4.4.6 Records of all inspections and analyses shall be maintained.

RESPONSE: COMPLIANT

2.4.5 Non-conforming Materials and Product

A Control of Non-Conforming Product Policy is in place. The policy was updated on Jun. 18, 2021. Anybody can stop the line and place product on hold. Only QA can release product from the hold status. Non-conforming product is tagged with a hold tag and placed on hold in SyteLine. When it is on hold in SyteLine the product cannot be used. Hold records are maintained. A hold log is maintained. The log will show what is on hold, reason, amount and disposition. The log was complete for Nov. and Dec. 2021.

2.4.5.1 The responsibility and methods outlining how to handle non-conforming product, raw material, ingredient, work-in-progress, or packaging, which is detected during receipt, storage, processing, handling, or delivery, shall be documented and implemented. The methods applied shall ensure: i. Non-conforming product is quarantined, identified, handled, and/or disposed of in a manner that minimizes the risk of inadvertent use, improper use, or risk to the integrity of finished product; and ii. All relevant personnel are aware of the organization's quarantine and release requirements applicable to product placed under quarantine status.

RESPONSE: COMPLIANT

2.4.5.2 Quarantine records and records of the handling, corrective action, or disposal of nonconforming materials or product shall be maintained.

RESPONSE: COMPLIANT

2.4.6 Product Rework

A Rework Policy is in place. The Policy was updated on Jul. 28, 2021. Rework is opening a bag that was not correct and placing it back into the same bag. Blow molding regrind is labeled and used back like resin into like. Records were maintained.

2.4.6.1 The responsibility and methods outlining how ingredients, packaging, or products are reworked shall be documented and implemented. The methods applied shall ensure: i. Reworking operations are overseen by qualified personnel; ii. Reworked product is clearly identified and traceable; iii. Reworked product is processed in accordance with the site's food safety plan; iv. Each batch of reworked product is inspected or analyzed as required before release; v. Inspections and analyses conform to the requirements outlined in element 2.4.4.1; vi. Release of reworked product conforms to element 2.4.7; and vii. Reworked product does not affect the safety or integrity of the finished product. Records of all reworking operations shall be maintained.

RESPONSE: COMPLIANT

2.4.7 Product Release (Mandatory)

A Raw Material and Finished Good Release Policy is in place. The policy was updated on Jul. 15, 2019. QA is responsible for releasing product. Product is considered released when the labels, packaging, weights and other attributes required are in specification. If testing is required the product is placed in a hold status for testing. Records for product release were reviewed for Jan. 11 - 13, Apr. 13 - 15, Jul. 14 - 16, and Nov. 16 - 18, 2021. The records were complete and verified.

2.4.7.1 The responsibility and methods for releasing products shall be documented and implemented. The methods applied shall ensure the product is released by authorized personnel, and only after all inspections and analyses are successfully completed and documented to verify legislative and other established food safety controls have been met. Records of all product releases shall be maintained.

RESPONSE: COMPLIANT

2.4.7.2 Product release shall include a procedure to confirm that product labels comply with the food legislation that applies in the country of manufacture and the country(ies) of use or sale if known (refer to 2.4.1.1). If product is packaged and distributed in bulk or unlabeled, product information shall be made available to inform customers and/or consumers of the requirements for its safe use.

RESPONSE: COMPLIANT

2.4.7.3 In the event that the site uses positive release based on product pathogen or chemical testing, a procedure shall be in place to ensure that product is not released until acceptable results have been received. In the event that off-site or contract warehouses are used, these requirements shall be effectively communicated and verified as being followed.

RESPONSE: COMPLIANT

2.4.8 Environmental Monitoring

An Environmental/Pathogen Monitoring Program is in place. The program was updated on Dec. 31, 2021. The tests for Salmonella and Listeria spp. Approximately 160 sites are taken from zone 2, 86 from zone 3 and 25 from zone 4 monthly for all sites combined. Sites are rotated on a quarterly basis. There are three sets of rotation. A corrective action was reviewed for a presumptive on a dock plate in Bentonville. The corrective action included vectoring and a root cause analysis. The vectoring was conducted for three days. Results were reviewed.

2.4.8.1 A risk-based environmental monitoring program shall be in place for all food manufacturing processes and immediate surrounding areas, which impact manufacturing processes. The responsibility and methods for the environmental monitoring program shall be documented and implemented.

RESPONSE: COMPLIANT

2.4.8.2 An environmental sampling and testing schedule shall be prepared. It shall at a minimum: i. Detail the applicable pathogens or indicator organisms to test for in that industry; ii. List the number of samples to be taken and the frequency of sampling; iii. Outline the locations in which samples are to be taken and the rotation of locations as needed; and iv. Describe the methods to handle elevated or undesirable results.

RESPONSE: COMPLIANT

2.4.8.3 Environmental testing results shall be monitored, tracked, and trended, and preventative actions (refer to 2.5.3.1) shall be implemented where unsatisfactory results or trends are observed.

RESPONSE: COMPLIANT

2.5.1 Validation and Effectiveness (Mandatory)

Methods are in place for the validation of the SQF Programs. The policy was updated on Sept. 30, 2020. The metal detectors/x-ray were validated Feb. and Mar. of 2021 for all sites. Allergens were validated Jan. 31, 2022, and pest control was validated for all three sites between Jan. 25 and 27, 2022. Records for all other validations were in place and complete.

2.5.1.1 The methods, responsibility, and criteria for ensuring the effectiveness of all applicable elements of the SQF Program shall be documented and implemented. The methods applied shall validate that: i. Good Manufacturing Practices are confirmed to ensure they achieve the required results; ii. Critical food safety limits are reviewed annually and re-validated or justified by regulatory standards when changes occur; and iii. Changes to the processes or procedures are assessed to ensure the controls are still effective. Records of all validation activities shall be maintained.

RESPONSE: COMPLIANT

2.5.2 Verification Activities (Mandatory)

A verification schedule is in place. The schedule includes the frequency of verification and who is responsible for the verification. The GMP's, metal detection/x-ray and line checks are verified daily. Records for the daily verifications were reviewed for Jan. 11 - 13, Apr. 13 - 15, Jul. 14 - 16, and Nov. 16 - 18, 2021. The records were complete and verified.

2.5.2.1 The methods, responsibility, and criteria for verifying monitoring of Good Manufacturing Practices, critical control points, and other food safety controls, and the legality of certified products shall be documented and implemented. The methods applied shall ensure that personnel with responsibility for verifying monitoring activities authorize each verified record.

RESPONSE: COMPLIANT

2.5.2.2 A verification schedule outlining the verification activities, their frequency of completion, and the person responsible for each activity shall be prepared and implemented. Records of verification of activities shall be maintained.

RESPONSE: COMPLIANT

2.5.3 Corrective and Preventative Action (Mandatory)

A Corrective Actions/Preventative Actions Program is in place. The program was updated on Apr. 17, 2020. Department heads, supervisors and quality can initiate a CAPA for audit findings, line issues, and customer complaints. CAPA's are required to include a root cause investigations. A CAPA was reviewed for a seal issue (complaint) dated May 13, 2021. Root cause was that the tester was not being used correctly. Records for all other CAPA's were maintained.

2.5.3.1 The responsibility and methods outlining how corrective and preventative actions are determined, implemented, and verified, including the identification of the root cause and resolution of non-compliance of critical food safety limits and deviations from food safety requirements, shall be documented and implemented. Deviations from food safety requirements may include customer complaints, nonconformances raised at internal or external audits and inspections, non-conforming product and equipment, withdrawals and recalls, as appropriate.

RESPONSE: COMPLIANT

2.5.3.2 Records of all investigation, root cause analysis, and resolution of non-conformities, their corrections, and the implementation of preventative actions shall be maintained.

RESPONSE: COMPLIANT

2.5.4 Internal Audits and Inspections (Mandatory)

An Internal Audit Program is in place. The program was updated on Jul. 9, 2018. An internal SQF audit was completed by Jan. 14, 2022. All areas of the code were covered. Issues found were documented along with the corrective actions. The non-conformance's were reviewed with management. Internal auditor training was completed on Jan. 10, 2022. Monthly audits are conducted at all three sites. The employees conducting the audits were independent of the areas being audited. The corrective actions were assigned and completed for Dec and Jan. 2022. Records for internal audits were reviewed for Dec. and Jan. 2022. Non-conformance's were assigned and completed.

2.5.4.1 The methods and responsibility for scheduling and conducting internal audits to verify the effectiveness of the SQF System shall be documented and implemented. Internal audits shall be conducted in full and at least annually. The methods applied shall ensure: i. All applicable requirements of the SQF Food Safety Code: Food Manufacturing are audited per the SQF audit checklist or a similar tool; ii. Objective evidence is recorded to verify compliance and/or non-compliance; iii. Corrective and preventative actions of deficiencies identified during the internal audits are undertaken; and iv. Audit results are communicated to relevant management personnel and staff responsible for implementing and verifying corrective and preventative actions.

RESPONSE: COMPLIANT

2.5.4.2 Staff conducting internal audits shall be trained and competent in internal audit procedures. Where practical, staff conducting internal audits shall be independent of the function being audited.

RESPONSE: COMPLIANT

2.5.4.3 Regular inspections of the site and equipment shall be planned and carried out to verify Good Manufacturing Practices and facility and equipment maintenance are compliant to the SQF Food Safety Code: Food Manufacturing. The site shall: i. Take corrections or corrective and preventative action; and ii. Maintain records of inspections and any corrective actions taken.

RESPONSE: COMPLIANT

2.5.4.4 Records of internal audits and inspections and any corrective and preventative actions taken as a result of internal audits shall be recorded as per 2.5.3. Changes implemented from internal audits that have an impact on the site's ability to deliver safe food shall require a review of applicable aspects of the SQF System (refer to 2.3.1.3).

RESPONSE: COMPLIANT

2.6.1 Product Identification (Mandatory)

Methods are in place for identification of ingredients. Ingredients are tagged with a license plate at time of receipt. The license plate is entered into SyteLine and includes the supplier information and lot code. The license plate is used to track the component through the system to the finished package. Start up and changeovers are in Q-works. The product and bar codes have to match the new product and label. Investigations will be conducted when label counts do not match. Labels used are accounted for at time of use. Records for product changeover and label reconciliations were reviewed for Jan. 11 - 13, Apr. 13 - 15, Jul. 14 - 16, and Nov. 16 - 18, 2021. The records were complete and verified.

2.6.1.1 The methods and responsibility for identifying raw materials, ingredients, packaging, work-in-progress, process inputs, and finished products during all stages of production and storage shall be documented and implemented to ensure: i. Raw materials, ingredients, packaging, work-in-progress, process inputs, and finished products are clearly identified during all stages of receipt, production, storage, and dispatch; and ii. Finished product is labeled to the customer specification and/or regulatory requirements.

RESPONSE: COMPLIANT

2.6.1.2 Product start-up, product changeover, and packaging changeover (including label changes) procedures shall be documented and implemented to ensure that the correct product is in the correct package and with the correct label and that the changeover is inspected and approved by an authorized person. Procedures shall be implemented to ensure that label use is reconciled and any inconsistencies investigated and resolved. Product changeover and label reconciliation records shall be maintained.

RESPONSE: COMPLIANT

2.6.2 Product Trace (Mandatory)

A Recall and Traceability Policy is in place. The policy was updated on Oct. 10, 2021. A trace exercise was conducted during the audit for Raisinetes packaged on Nov. 15, 2021. 539 cases were packaged. The raisenetes were received on Oct. 29, 2021. The bags were received on Sept. 17, 2021. 100% of the product was shipped to one DC on Nov. 24, 2021. The documentation reviewed was complete. Records of receipt and dispatch were maintained.

2.6.2.1 The responsibility and methods used to trace product shall be documented and implemented to ensure: i. Finished product is traceable at least one step forward to the customer and at least one step back from the process to the manufacturing supplier; ii. The receipt dates of raw materials, ingredients, food contact packaging and materials, and other inputs are recorded (refer to 2.8.1.8 for traceback of allergen containing food products.); iii. Traceability is maintained where product is reworked (refer to 2.4.6); and iv. The effectiveness of the product trace system is reviewed at least annually, as part of the product recall and withdrawal review (refer to 2.6.3.2). Records of raw and packaging material receipt and use and finished product dispatch and destination shall be maintained.

RESPONSE: COMPLIANT

2.6.3 Product Withdrawal and Recall (Mandatory)

A Recall and Traceability Procedure is in place. The procedure was updated on Oct. 10, 2021. The Director of Food Safety is responsible for initiating a recall. A recall team is also in place. Communication to customers is by the account manager. Internal and external communications are conducted by the Director of Food Safety. A phone list is in place which includes legal and expert advice, SQFI and the CB. Investigations will be undertaken to find the root cause in the event of a recall. The CB and SQFI will be notified within 24 hrs of a recall or withdrawal. The site has not had a recall since the last SQF audit. A mock recall was conducted on Jul. 28, 2021. The mock was for apple pumpkin spice pieces (raw material). 100 % of the raw material and product was accounted for in one hour. Documentation reviewed was complete.

2.6.3.1 The responsibility and methods used to withdraw or recall product shall be documented and implemented. The procedure shall: i. Identify those responsible for initiating, managing, and investigating a product withdrawal or recall; ii. Describe the management procedures to be implemented, including sources of legal, regulatory, and expert advice, and essential traceability information; iii. Outline a communication plan to inform site personnel, customers, consumers, authorities, and other essential bodies in a timely manner appropriate about the nature of the incident; and iv. Ensure that SQFI, the certification body, and the appropriate regulatory authority are listed as essential organizations and notified in instances of a food safety incident of a public nature or product recall for any reason.

RESPONSE: COMPLIANT

2.6.3.2 The product withdrawal and recall system shall be reviewed, tested, and verified as effective at least annually. Testing shall include incoming materials (minimum traceability one step back) and finished product (minimum traceability one step forward). Testing shall be carried out on products from different shifts and for materials (including bulk materials) that are used across a range of products and/or products that are shipped to a wide range of customers.

RESPONSE: COMPLIANT

2.6.3.3 Records shall be maintained of withdrawal and recall tests, root cause investigations into actual withdrawals and recalls, and corrective and preventative actions applied.

RESPONSE: COMPLIANT

2.6.3.4 SQFI and the certification body shall be notified in writing within twenty-four (24) hours upon identification of a food safety event that requires public notification. SQFI shall be notified at foodsafetycrisis@sqfi.com.

RESPONSE: COMPLIANT

2.6.4 Crisis Management Planning

A Crisis Management Plan is in place. The plan was last updated on May 14, 2021. The plan includes all potential threats that could affect the site. The Chief Operating officer is the senior manager responsible for decision making during a crisis. A crisis management team is also in place. Each member is responsible for specific decision making during a crisis. The Director of Food Safety is responsible for internal and external communications. Any product/ingredient that is affected is placed on hold. All products are inspected prior to dispositioning the ingredient or product by QA. A crisis contact list is in place. The list includes legal and expert advice. A test of the plan was conducted on May 14, 2021 for loss of power at the Bartlett facility. The facility was down for 28.5 hrs. No products or customers were affected.

2.6.4.1 A crisis management plan based on the understanding of known potential dangers (e.g., flood, drought, fire, tsunami, or other severe weather events, warfare or civil unrest, computer outage, pandemic, loss of electricity or refrigeration, ammonia leak, labor strike) that can impact the site's ability to deliver safe food shall be documented by senior management, outlining the methods and responsibility the site shall implement to cope with such a business crisis. The crisis management plan shall include at a minimum: i. A senior manager responsible for decision making, oversight, and initiating actions arising from a crisis management incident; ii. The nomination and training of a crisis management team; iii. The controls implemented to ensure any responses do not compromise product safety; iv. The measures to isolate and identify product affected by a response to a crisis; v. The measures taken to verify the acceptability of food prior to release; vi. The preparation and maintenance of a current crisis alert contact list, including supply chain customers; vii. Sources of legal and expert advice; and viii. The responsibility for internal communications and communicating with authorities, external organizations, and media.

RESPONSE: COMPLIANT

2.6.4.2 The crisis management plan shall be reviewed, tested, and verified at least annually with gaps and appropriate corrective actions documented. Records of reviews of the crisis management plan shall be maintained.

RESPONSE: COMPLIANT

2.7.1 Food Defense Plan (Mandatory)

A Food Defense & Bio-Security program is in place. The program reassessed on May 21, 2021. The Safety and Security Manager is responsible for maintaining the program. A food defense team is also in place. The plan includes methods for controlling access for employees and how chemicals are stored. Visitors and contactors are required to sign in at the front office. All incoming and outbound shipments are required to be sealed or locked. Doors that were required to be locked during the audit were locked. A test was conducted for accessing the buildings try to get into the buildings. The sites passed.

2.7.1.1 A food defense threat assessment shall be conducted to identify potential threats that can be caused by a deliberate act of sabotage or terrorist-like incident.

RESPONSE: COMPLIANT

2.7.1.2 A food defense plan shall be documented, implemented, and maintained based on the threat assessment (refer to 2.7.1.1). The food defense plan shall meet legislative requirements as applicable and shall include at a minimum: i. The methods, responsibility, and criteria for preventing food adulteration caused by a deliberate act of sabotage or terrorist-like incident; ii. The name of the senior site management person responsible for food defense; iii. The methods implemented to ensure only authorized personnel have access to production equipment and vehicles, manufacturing, and storage areas through designated access points; iv. The methods implemented to protect sensitive processing points from intentional adulteration; v. The measures taken to ensure the secure receipt and storage of raw materials, ingredients, packaging, equipment, and hazardous chemicals to protect them from deliberate acts of sabotage or terrorist-like incidents; vi. The measures implemented to ensure raw materials, ingredients, packaging (including labels), work-in-progress, process inputs, and finished products are held under secure storage and transportation conditions; and vii. The methods implemented to record and control access to the premises by site personnel, contractors, and visitors.

RESPONSE: COMPLIANT

2.7.1.3 Instruction shall be provided to all relevant staff on the effective implementation of the food defense plan (refer to 2.9.2.1).

RESPONSE: COMPLIANT

2.7.1.4 The food defense threat assessment and prevention plan shall be reviewed and tested at least annually or when the threat level, as defined in the threat assessment, changes. Records of reviews and tests of the food defense plan shall be maintained.

RESPONSE: COMPLIANT

2.7.2 Food Fraud (Mandatory)

A Food Fraud Plan is in place. The plan was reassessed on May 10, 2021. Components supplied by customers have gone through the customers food fraud assessment. Mitigation for food fraud is between the customer and the company. Food defense and quality checks are also used to mitigate food fraud. Records of the reviews were maintained.

2.7.2.1 The methods, responsibility, and criteria for identifying the site's vulnerability to food fraud, including susceptibility to raw material or ingredient substitution, finished product mislabeling, dilution, or counterfeiting, shall be documented, implemented, and maintained.

RESPONSE: COMPLIANT

2.7.2.2 A food fraud mitigation plan shall be developed and implemented that specifies the methods by which the identified food fraud vulnerabilities shall be controlled, including identified food safety vulnerabilities of ingredients and materials.

RESPONSE: COMPLIANT

2.7.2.3 Instruction shall be provided to all relevant staff on the effective implementation of the food fraud mitigation plan (refer to 2.9.2.1).

RESPONSE: COMPLIANT

2.7.2.4 The food fraud vulnerability assessment and mitigation plan shall be reviewed and verified at least annually with gaps and corrective actions documented. Records of reviews shall be maintained.

RESPONSE: COMPLIANT

2.8.1 Allergen Management (Mandatory)

An Allergen Control Program is in place. The program was updated on Jan. 31, 2022. All employees are responsible for the program. A risk analysis for allergens was conducted. The facilities have identified wheat, egg, soy, dairy, fish, shellfish, peanuts and tree nuts. Allergens are identified at time of receipt in WMS and stored in specific areas. Complete sanitation is performed between allergens and the sanitation is documented. Bentonville has a dedicated room for running allergens. Sanitation is verified with ATP swabbing. The product identification system includes the identification of allergens. Finished product labels are verified at time of receipt and at time of use. The product trace system includes the allergens. Re-working is like into like only. The products are labeled. Allergen training is conducted annually.

2.8.1.1 The responsibility and methods used to control allergens and to prevent sources of allergens from contaminating product shall be documented and implemented. The allergen management program shall include: i. A risk analysis of those raw materials, ingredients, and processing aids, including food grade lubricants, that contain food allergens; ii. An assessment of workplace-related food allergens that may originate from locker rooms, vending machines, lunchrooms, and visitors; iii. A list of allergens that is applicable in the country of manufacture and the country(ies) of destination, if known; iv. A list of allergens that is accessible to relevant staff; v. The control of hazards associated with allergens and incorporated into the food safety plan, and vi. Management plans for control of the identified allergens.

RESPONSE: COMPLIANT

2.8.1.2 Instructions shall be provided to all relevant staff involved in the receipt or handling of raw materials, work-in-progress, rework, or finished product on how to identify, handle, store, and segregate raw materials and products containing allergens.

RESPONSE: COMPLIANT

2.8.1.3 Provisions shall be made to clearly identify and segregate foods that contain allergens. Segregation procedures shall be implemented and continually monitored.

RESPONSE: COMPLIANT

2.8.1.4 Where allergenic material may be intentionally or unintentionally present cleaning and sanitation of product contact surfaces between line changeovers shall be effective, appropriate to the risk and legal requirements, and sufficient to remove all potential target allergens from product contact surfaces, including aerosols as appropriate, to prevent cross-contact. Separate handling and production equipment shall be provided, where satisfactory line hygiene and clean-up or segregation are not possible.

RESPONSE: COMPLIANT

2.8.1.5 Based on risk assessment, procedures for validation and verification of the effectiveness of the cleaning and sanitation of areas and equipment in which allergens are used shall be documented and effectively implemented.

RESPONSE: COMPLIANT

2.8.1.6 Where allergenic material may be present, product changeover procedures shall be documented and implemented to eliminate the risk of cross-contact.

RESPONSE: COMPLIANT

2.8.1.7 The product identification system (refer to 2.6.1.1) shall make provision for clear identification and labeling, in accordance with the regulatory requirements of those products produced on production lines and equipment on which foods containing allergens are manufactured.

RESPONSE: COMPLIANT

2.8.1.8 The product trace system (refer to 2.6.2) shall take into consideration the conditions under which allergen-containing foods are manufactured and ensure full traceback of all ingredients and processing aids used.

RESPONSE: COMPLIANT

2.8.1.9 The site shall document and implement methods to control the accuracy of finished product labels (or consumer information where applicable) and assure work-in progress and finished product are true to label with regard to allergens. Measures may include label approvals at receipt, label reconciliations during production, destruction of obsolete labels, verification of labels on finished product as appropriate, and product change over procedures.

RESPONSE: COMPLIANT

2.8.1.10 Re-working of product (refer to 2.4.6) containing food allergens shall be conducted under conditions that ensure product safety and integrity are maintained. Re-worked product containing allergens shall be clearly identified and traceable.

RESPONSE: COMPLIANT

2.8.1.11 Sites that do not handle allergenic materials or produce allergenic products shall document, implement and maintain an allergen management program addressing at a minimum the mitigation of introduced or unintended allergens through supplier, contract manufacturer, site personnel, and visitor activities.

RESPONSE: COMPLIANT

2.9.1 Training Requirements

The SQF practitioner and supervisors are responsible for training at the facilities. SQF training and PCQI training were completed by the SQF Practitioner.

2.9.1.1 The responsibility for establishing and implementing the training needs of the organization's personnel to ensure they have the required competencies to carry out those functions affecting products, legality, and safety shall be defined and documented (refer to 2.1.1.6).

RESPONSE: COMPLIANT

2.9.1.2 Appropriate training shall be provided for personnel carrying out the tasks essential to the effective implementation of the SQF System and the maintenance of food safety and regulatory requirements.

RESPONSE: COMPLIANT

2.9.2 Training Program (Mandatory)

A Training Program is in place. The program was updated on Aug. 25, 2020. Training is conducted in Alchemy at time of hire and annually. Training includes personal hygiene, HACCP, allergens, preventative Food borne illness, facility defense, food safety standards, foreign material, guiding principles and workplace safety, general quality/mission statement. Job specific training is also completed. CCP training is conducted annually. Training is conducted in English and Spanish which is understood by all employees. Training records were maintained in Alchemy. The records were current for the employees reviewed. Quizzes are given to verify training.

2.9.2.1 A training program shall be documented and implemented that at a minimum outlines the necessary competencies for specific duties and the training methods to be applied to personnel carrying out tasks associated with: i. Implementing HACCP for staff involved in developing and maintaining food safety plans; ii. Monitoring and corrective action procedures for all staff engaged in monitoring critical control points (CCPs); iii. Personal hygiene for all staff involved in the handling of food products and food contact surfaces; iv. Good Manufacturing Practices and work instructions for all staff engaged in food handling, food processing, and equipment; v. Sampling and test methods for all staff involved in sampling and testing of raw materials, packaging, work-in-progress, and finished products; vi. Environmental monitoring for relevant staff; vii. Allergen management, food defense, and food fraud for all relevant staff; and viii. Tasks identified as critical to meeting the effective implementation and maintenance of the SQF code. The training program shall include provisions for identifying and implementing the refresher training needs of the organization.

RESPONSE: COMPLIANT

2.9.2.2 Training materials, the delivery of training, and procedures on all tasks critical to meeting regulatory compliance and the maintenance of food safety shall be provided in language(s) understood by staff.

RESPONSE: COMPLIANT

2.9.2.3 Training records shall be maintained and include: i. Participant name; ii. Skills description; iii. Description of the training provided; iv. Date training completed; v. Trainer or training provider; and vi. Verification that the trainee is competent to complete the required tasks.

RESPONSE: COMPLIANT

11.1.1 Premises Location and Approval

The sites are located in industrial areas. The exterior of the sites are monitored during the monthly audits. The sites are registered with the FDA. The registration expires on Dec. 31, 2022.

11.1.1.1 The site shall assess local activities and the site environment to identify any risks that may have an adverse impact on product safety and implement controls for any identified risks. The assessment shall be reviewed in response to any changes in the local environment or activities. The construction and ongoing operation of the premises on the site shall be approved by the relevant authority.

RESPONSE: COMPLIANT

11.1.2 Building Materials

Floors were in overall good condition. Drains are located in the sanitation rooms in all facilities. There are no drains in production. The drains were in good condition. A risk analysis was conduct in May 2021 for all 3 facilities for ducting and piping along with wastewater pipes. The risk analysis showed the pipes were in good condition and did not pose a contamination risk. The piping was in good condition. Doors and windows were in good condition and of solid construction. Windows were constructed of shatterproof materials. Ceilings were in overall good condition. Platforms and stairs over production lines were in good condition and of solid construction.

11.1.2.1 Floors shall be constructed of smooth, dense, impact-resistant material that can be effectively graded, drained, impervious to liquid, and easily cleaned. Floors shall be sloped to floor drains at gradients suitable to allow the effective removal of all overflow or wastewater under normal working conditions. Where floor drainage is not available, plumbed options to handle overflow or wastewater shall be in place.

RESPONSE: COMPLIANT

11.1.2.2 Drains shall be constructed and located so they can be easily cleaned and not present a hazard.

RESPONSE: COMPLIANT

11.1.2.3 Waste trap system shall be located away from any food handling areas or entrances to the premises.

RESPONSE: COMPLIANT

11.1.2.4 Walls, partitions, ceilings, and doors shall be of durable construction. Internal surfaces shall have an even and regular surface and be impervious with a light-colored finish and shall be kept clean (refer to 11.2.5). Wall-to-wall and wall-to-floor junctions shall be designed to be easily cleaned and sealed to prevent the accumulation of food debris.

RESPONSE: MINOR

EVIDENCE: In the 50 and 70 line in Bentonville, there was a gap along the top of the perimeter of the interior wall.

ROOT CAUSE: No one had identified there was a gap at the top of the interior perimeter wall.

CORRECTIVE ACTION: Gap was closed on the interior perimeter wall

VERIFICATION OF CLOSEOUT: Reviewed the picture and approved the corrective action.

COMPLETION DATE: 02/21/2022 **CLOSEOUT DATE:** 02/24/2022

11.1.2.5 Ducting, conduit, and pipes that convey ingredients, products, or services, such as steam or water, shall be designed and constructed to prevent the contamination of food, ingredients, and food contact surfaces and allow ease of cleaning. A risk analysis shall be conducted to ensure food contamination risks are mitigated.

RESPONSE: COMPLIANT

11.1.2.6 Pipes carrying sanitary waste or wastewater that are located directly over product lines or storage areas shall be designed and constructed to prevent the contamination of food, materials, ingredients, and food contact surfaces and shall allow ease of cleaning. A risk analysis shall be conducted to ensure food contamination risks are mitigated.

RESPONSE: COMPLIANT

11.1.2.7 Doors, hatches, and windows and their frames in food processing, handling, or storage areas shall be of a material and construction that meets the same functional requirements as for internal walls and partitions. Doors and hatches shall be of solid construction, and windows shall be made of shatterproof glass or similar material.

RESPONSE: COMPLIANT

11.1.2.8 Product shall be processed and handled in areas that are fitted with a ceiling or other acceptable structure that is constructed and maintained to prevent the contamination of products. Drop ceilings, where present, shall be constructed to enable monitoring for pest activity, facilitate cleaning, and provide access to utilities.

RESPONSE: COMPLIANT

11.1.2.9 Stairs, catwalks, and platforms in food processing and handling areas shall be designed and constructed so they do not present a product-contamination risk and with no open grates directly above exposed food product surfaces. They shall be kept clean (refer to 11.2.5).

RESPONSE: COMPLIANT

11.1.3 Lightings and Light Fittings

There were an adequate amount of light in the processing areas. The light fittings were shielded with shatterproof shields. Light fittings in the warehouse areas were shielded. All shields were in good condition and clean.

11.1.3.1 Lighting in food processing and handling areas and at inspection stations shall be of appropriate intensity to enable the staff to carry out their tasks efficiently and effectively and shall comply with local light-intensity regulations or industry standards.

RESPONSE: COMPLIANT

11.1.3.2 Light fixtures in processing areas, inspection stations, ingredient and packaging storage areas, and all areas where the product is exposed shall be shatterproof, manufactured with a shatterproof covering or fitted with protective covers, and recessed into or fitted flush with the ceiling. Where fixtures cannot be recessed, structures must be protected from accidental breakage, manufactured from cleanable materials, and addressed in the cleaning and sanitation program.

RESPONSE: COMPLIANT

11.1.3.3 Light fixtures in the warehouse or other areas where product is covered or otherwise protected shall be designed to prevent breakage and product contamination.

RESPONSE: COMPLIANT

11.1.4 Inspection/ Quality Control Area

Inspection stations were provided by the lines for the inspection of product. The stations were equipped with scales and computers. The stations had access to hand wash stations, and waste containment. The stations were clean.

11.1.4.1 If online inspection is required, a suitable area close to the processing line shall be provided for the inspection of product (refer to 2.4.4). The inspection/quality control area shall be provided with facilities that are suitable for examination and testing of the type of product being handled/processed. The inspection area shall: i. Have easy access to handwashing facilities; ii. Have appropriate waste handling and removal; and iii. Be kept clean to prevent product contamination.

RESPONSE: COMPLIANT

11.1.5 Dust, Insect, and Pest Proofing

External windows and doors were sealed. External doors are provided. The doors were self closing and insect proofed. There was an adequate amount of sealing around the trailers in the dock doors. Electric insect devices are located away from product. No bait was used inside the buildings.

11.1.5.1 All external windows, ventilation openings, doors, and other openings shall be effectively sealed when closed, and proofed against dust, vermin, and other pests. External personnel access doors shall be effectively insect-proofed and fitted with a self-closing device and proper seals to protect against entry of dust, vermin, and other pests.

RESPONSE: COMPLIANT

11.1.5.2 External doors, including overhead dock doors in food handling areas used for product, pedestrian, or truck access, shall be designed and maintained to prevent pest ingress by at least one or a combination of the following methods: i. A self-closing device; ii. An effective air curtain; iii. A pest-proof screen; iv. A pest-proof annex; and v. Adequate sealing around trucks in docking areas.

RESPONSE: COMPLIANT

11.1.5.3 Electric insect control devices, pheromone, or other traps and baits shall be located and operated so they do not present a contamination risk to the product, packaging, containers, or processing equipment. Poison rodenticide bait shall not be used inside ingredients or product storage areas or processing areas where ingredients, packaging, and products are handled, processed, or exposed.

RESPONSE: COMPLIANT

11.1.6 Ventilation

There was an adequate amount of ventilation in the facilities. Fans were in good condition and clean. There were no cooking operations.

11.1.6.1 Adequate ventilation shall be provided in enclosed processing and food handling areas. Where appropriate, positive air-pressure systems shall be installed to prevent airborne contamination.

RESPONSE: COMPLIANT

11.1.6.2 All ventilation equipment and devices in product storage and handling areas shall be adequately cleaned as per 11.2.5 to prevent unsanitary conditions.

RESPONSE: COMPLIANT

11.1.6.3 Extractor fans and canopies shall be provided in areas where open cooking operations are carried out or a large amount of steam is generated. Capture velocities shall be sufficient to prevent condensation build-up and to evacuate all heat, fumes, and other aerosols to the exterior via an exhaust hood positioned over the cooker(s).

RESPONSE: NOT APPLICABLE

EVIDENCE: There were no cooking operations.

11.1.6.4 Fans and exhaust vents shall be insect-proofed and located so they do not pose a contamination risk and shall be kept clean.

RESPONSE: NOT APPLICABLE

EVIDENCE: There were no cooking operations.

11.1.7 Equipment and Utensils

Specifications are in place for utensils, equipment and protective clothing. New equipment is purchased by Engineering. Sanitation, operations and QC must sign off on the equipment. The equipment must be of sanitary design. Equipment was in overall good condition and installed to allow for cleaning. Equipment storage areas were located to allow for cleaning and the areas were clean. Product and non-product contact surfaces were in good condition. The surfaces were manufactured from materials suitable for the industry. Tables, conveyors and scales were in good condition. No rough welds or cracks were observed. Product containers were labeled and color coded. The containers were constructed from materials appropriate for the industry. Inedible materials were identified. Equipment and utensils are cleaned after use. Battery operated forklifts are used in the plant. Non-conforming equipment is tagged. Any equipment that is disposed off will be documented.

11.1.7.1 Specifications for equipment and utensils and procedures for purchasing equipment shall be documented and implemented.

RESPONSE: COMPLIANT

11.1.7.2 Equipment and utensils shall be designed, constructed, installed, operated, and maintained to meet any applicable regulatory requirements and to not pose a contamination threat to products.

RESPONSE: COMPLIANT

11.1.7.3 Equipment storage rooms shall be designed and constructed to allow for the hygienic and efficient storage of equipment and containers. Where possible, food contact equipment shall be segregated from non-food contact equipment.

RESPONSE: COMPLIANT

11.1.7.4 Product contact surfaces and those surfaces not in direct contact with food in food handling areas, raw material storage, packaging storage, and cold storage areas shall be constructed of materials that will not contribute to a food safety risk.

RESPONSE: COMPLIANT

11.1.7.5 Benches, tables, conveyors, mixers, mincers, graders, and other mechanical processing equipment shall be hygienically designed and located for appropriate cleaning. Equipment surfaces shall be smooth, impervious, and free from cracks or crevices.

RESPONSE: COMPLIANT

11.1.7.6 Product containers, tubs, and bins used for edible and inedible material shall be constructed of materials that are non-toxic, smooth, impervious, and readily cleaned as per 11.2.5.1. Bins used for inedible material shall be clearly identified.

RESPONSE: COMPLIANT

11.1.7.7 All equipment and utensils shall be cleaned after use (refer to 11.2.5.1) or at a set and validated frequency to control contamination and be stored in a clean and serviceable condition to prevent microbiological or cross-contact allergen contamination.

RESPONSE: COMPLIANT

11.1.7.8 Vehicles used in food contact, handling, or processing zones or cold storage rooms shall be designed and operated so as not to present a food safety hazard.

RESPONSE: COMPLIANT

11.1.7.9 Non-conforming equipment shall be identified, tagged, and/or segregated for repair or disposal in a manner that minimizes the risk of inadvertent use, improper use, or risk to the integrity of finished product. Records of the handling, corrective action, and/or disposal of non-conforming equipment shall be maintained.

RESPONSE: COMPLIANT

11.1.8 Grounds and Roadways

The surrounding areas were in overall good condition. No waste or debris build up was observed. No harborage areas were observed. Paths and roadways were in overall good condition. No water was observed by the dock doors. Paths from amenities were paved. The exterior of the Elk Grove facility was not audited due to snow.

11.1.8.1 A suitable external environment shall be established, and the effectiveness of the measures shall be monitored and periodically reviewed. The premises, its surrounding areas, storage facilities, machinery, and equipment shall be kept free of waste or accumulated debris, and vegetation shall be controlled so as not to attract pests and vermin or present a food safety hazard to the sanitary operation of the site.

RESPONSE: COMPLIANT

11.1.8.2 Paths, roadways, and loading and unloading areas shall be maintained so as not to present a hazard to the food safety operations of the premises. They shall be adequately drained to prevent the pooling of water. Drains shall be separate from the site drainage system and regularly cleared of debris.

RESPONSE: COMPLIANT

11.1.8.3 Paths from amenities leading to site entrances shall be effectively sealed.

RESPONSE: COMPLIANT

11.2.1 Repairs and Maintenance

A Preventative Maintenance Program is in place. The Preventative Maintenance Schedule is maintained in CMMS. The PM's cover all areas of the facilities. Weekly work orders are generated and then completed during the week. The completed work orders are documented in CMMS. Records reviewed for Dec. 2021 were complete. Failures of plant equipment are documented and are used to adjust the PM schedule if required. Supervisors are notified when maintenance is to be completed in their area. If maintenance will impact product, the line is shut down and repairs are completed after production. If temporary repairs are used the work order can be marked as waiting for parts. When the part is received and the work completed, the work order is closed out. Only food grade lubricants were used in the processing areas. The food grade lubricants were stored separate from non-food grade lubricants. Paint was not observed on product contact zones.

11.2.1.1 The methods and responsibility for the maintenance and repair of plant, equipment, and buildings shall be documented, planned, and implemented in a manner that minimizes the risk of product, packaging, or equipment contamination.

RESPONSE: COMPLIANT

11.2.1.2 Routine maintenance of plant and equipment in any food processing, handling, or storage areas shall be performed according to a maintenance control schedule and recorded. The maintenance schedule shall be prepared to include buildings, equipment, and other areas of the premises critical to the maintenance of product safety.

RESPONSE: COMPLIANT

11.2.1.3 Failures of plant and equipment in any food processing, handling, or storage areas shall be documented and reviewed, and their repair(s) incorporated into the maintenance control schedule.

RESPONSE: COMPLIANT

11.2.1.4 Site supervisors shall be notified when maintenance or repairs are to be undertaken in any processing, handling, or storage areas.

RESPONSE: COMPLIANT

11.2.1.5 The maintenance supervisor and the site supervisor shall be informed if any repairs or maintenance activities pose a potential threat to product safety (e.g., pieces of electrical wire, damaged light fittings, and loose overhead fittings). When possible, maintenance is to be conducted outside operating times.

RESPONSE: COMPLIANT

11.2.1.6 Temporary repairs, where required, shall not pose a food safety risk and shall be included in routine inspections (refer to 2.5.4.3) and the cleaning program. There shall be a plan in place to address the completion of temporary repairs to ensure they do not become permanent solutions.

RESPONSE: COMPLIANT

11.2.1.7 Food contact equipment and equipment located over food contact equipment shall be lubricated with food-grade lubricant, and its use shall be controlled to minimize the contamination of the product.

RESPONSE: COMPLIANT

11.2.1.8 Paint used in a food handling or processing area shall be suitable for use, in good condition, and not be used on any product contact surfaces.

RESPONSE: COMPLIANT

11.2.2 Maintenance Staff and Contractors

Maintenance employees were observed following plant GMP requirements. Contractors and employees are trained on GMP's. Contractors are escorted at all times. If work is required to be completed on a piece of equipment the work is performed. Tools and parts are accounted for. Sanitation is documented on the Line Clearance Sheet.

11.2.2.1 Maintenance staff and contractors shall comply with the site's personnel and process hygiene requirements (refer to 11.3).

RESPONSE: COMPLIANT

11.2.2.2 All maintenance and other engineering contractors required to work on-site shall be trained in the site's food safety and hygiene procedures or shall be escorted at all times until their work is completed.

RESPONSE: COMPLIANT

11.2.2.3 Maintenance staff and contractors shall remove all tools and debris from any maintenance activity once it has been completed, and inform the area supervisor and maintenance supervisor, so appropriate hygiene and sanitation can be conducted and a pre-operational inspection completed prior to the restarting of site operations.

RESPONSE: COMPLIANT

11.2.3 Calibration

A Calibration Work instruction is in place. The Work instruction was updated on Jul. 21, 2021. Equipment is calibrated against NIST standards or equipment specific standards. Calibrations are performed per regulatory and equipment requirements. The policy includes what to do with product should calibrated equipment be found to be out of calibration. Calibrated testing equipment is protected from unauthorized adjustments and damage. A register of equipment that requires calibration is maintained and was current. Metal Detectors were calibrated on May 17, 2021, X-rays were calibrated on May 17 and 19, 2021. Scales and checkweighers were calibrated on Dec. 29 thru Jan. 5, 2022.

11.2.3.1 The methods and responsibility for calibration and re-calibration of measuring, testing, and inspection equipment used for monitoring activities outlined in prerequisite programs, food safety plans, and other process controls, or to demonstrate compliance with customer specifications, shall be documented and implemented. Software used for such activities shall be validated as appropriate.

RESPONSE: COMPLIANT

11.2.3.2 Equipment shall be calibrated against national or international reference standards and methods or to an accuracy appropriate to its use. In cases where standards are not available, the site shall provide evidence to support the calibration reference method applied.

RESPONSE: COMPLIANT

11.2.3.3 Calibration shall be performed according to regulatory requirements and/or to the equipment manufacturers' recommended schedule.

RESPONSE: COMPLIANT

11.2.3.4 Procedures shall be documented and implemented to address the resolution of potentially affected products when measuring, testing, or inspection equipment is found to be out of calibration.

RESPONSE: COMPLIANT

11.2.3.5 Calibrated measuring, testing, and inspection equipment shall be protected from damage and unauthorized adjustment or use.

RESPONSE: COMPLIANT

11.2.3.6 A directory of measuring, testing, and inspection equipment that require calibration and records of the calibration tests shall be maintained.

RESPONSE: COMPLIANT

11.2.4 Pest Prevention

A Pest Control Program is in place. The program includes the methods used for pest prevention and methods for eliminating pests when required. The PCO reports to quality with findings. The interior devices are checked weekly on the interior and monthly on exterior of the facilities. Device maps were in place. The maps were updated on Jan 25, 2022. A list of approved chemicals is in place. The list was updated Jan 31, 2022. The chemicals were approved by the EPA. Only approved chemicals were used in the facility. SDS sheets were maintained electronically. Records of chemical applications were maintained. Only approved chemicals were used. Chemicals were applied by a licensed PCO. The PCO is licensed by the IDPH. The license expires on Dec. 31, 2023. Records for pest control were reviewed for Sept thru Jan. 2022. The records included the chemicals used and issues identified. If pest activity occurs in the plant, the area is treated. Any affected products or ingredients are disposed off and the disposal will be documented. Pesticides were not stored at the sites. No animals were allowed in the facilities.

11.2.4.1 A documented pest prevention program shall be effectively implemented. It shall: i. Describe the methods and responsibility for the development, implementation, and maintenance of the pest prevention program; ii. Record pest sightings and trend the frequency of pest activity to target pesticide applications; iii. Outline the methods used to prevent pest problems; iv. Outline the pest elimination methods and the appropriate documentation for each inspection; v. Outline the frequency with which pest status is to be checked; vi. Include the identification, location, number, and type of applied pest control/monitoring devices on a site map; vii. List the chemicals used. The chemicals are required to be approved by the relevant authority and their Safety Data Sheets (SDS) made available; viii. Outline the methods used to make staff aware of the bait control program and the measures to take when they come into contact with a bait station; ix. Outline the requirements for staff awareness and training in the use of pest and vermin control chemicals and baits; and x. Measure the effectiveness of the program to verify the elimination of applicable pests and to identify trends.

RESPONSE: COMPLIANT

11.2.4.2 Pest contractors and/or internal pest controllers shall: i. Be licensed and approved by the local relevant authority; ii. Use only trained and qualified operators, who comply with regulatory requirements; iii. Use only approved chemicals; iv. Provide a pest prevention plan (refer to 2.3.2.8), which includes a site map, indicating the location of bait stations traps and other applicable pest control/monitoring devices; v. Report to a responsible authorized person on entering the premises and after the completion of inspections or treatments; vi. Provide regular inspections for pest activity with appropriate action taken if pests are present, and vii. Provide a written report of their findings and the inspections and treatments applied.

RESPONSE: COMPLIANT

11.2.4.3 Pest activity risks shall be analyzed and recorded. Inspections for pest activity shall be conducted on a regular basis by trained site personnel and the appropriate action taken if pests are present. Identified pest activity shall not present a risk of contamination to food products, raw materials, or packaging. Records of all pest control inspections and applications shall be maintained.

RESPONSE: COMPLIANT

11.2.4.4 Food products, raw materials, or packaging that are found to be contaminated by pest activity shall be effectively disposed of, and the source of pest infestation shall be investigated and resolved. Records shall be kept of the disposal, investigation, and resolution.

RESPONSE: COMPLIANT

11.2.4.5 Pesticides shall be clearly labeled and stored per 11.6.4 if kept on-site.

RESPONSE: COMPLIANT

11.2.4.6 No animals shall be permitted on-site in food handling and storage areas.

RESPONSE: COMPLIANT

11.2.5 Cleaning and Sanitation

A master sanitation schedule is in place. The sanitation schedules include what is to be cleaned, frequency of cleaning and who is responsible for the cleaning. Verification of sanitation is with ATP swabs and visual inspections. A list of approved chemicals is maintained. The list was current. Inventory for chemicals is completed monthly by the chemical company. Letters of guarantee are in place for the chemicals stating that they are safe to use in a food facility. The letters were dated Jan. 31, 2018. SDS sheets are in place for all chemicals. The titrations are verified during the monthly service. An inventory of chemicals is conducted monthly. The sites do not have a CIP system. Clean parts are stored on racks and marked as clean. Sanitation rooms are in place for cleaning parts and equipment. Line Clearance checks are conducted by QA. (Pre-op). Employee amenities are checked during the monthly plant audits. Approximately 20 ATP swabs are completed after sanitation. Pre-operational inspections were reviewed for Jan. 2022. Sanitation records were complete for Jun. thru Dec. 2021.

11.2.5.1 The methods and responsibility for the effective cleaning of the food handling and processing equipment and environment and storage areas shall be documented and implemented. Consideration shall be given to: i. What is to be cleaned; ii. How it is to be cleaned; iii. When it is to be cleaned; iv. Who is responsible for the cleaning; v. Validation of the cleaning procedures for food contact surfaces (including CIP); vi. Methods used to confirm the correct concentrations of detergents and sanitizers; and vii. The responsibility and methods used to verify the effectiveness of the cleaning and sanitation program.

RESPONSE: COMPLIANT

11.2.5.2 Detergents and sanitizers shall be suitable for use in a food manufacturing environment, labeled according to regulatory requirements, and purchased in accordance with applicable legislation. The organization shall ensure: i. The site maintains a list of chemicals approved for use; ii. An inventory of all purchased and used chemicals is maintained; iii. Detergents and sanitizers are stored as outlined in element 11.6.4; iv. Safety Data Sheets (SDS) are provided for all detergents and sanitizers purchased; and v. Only trained staff handle sanitizers and detergents.

RESPONSE: COMPLIANT

11.2.5.3 Detergents and sanitizers that have been mixed for use shall be correctly mixed according to the manufacturers' instructions, stored in containers that are suitable for use, and clearly identified. Mix concentrations shall be verified and records maintained.

RESPONSE: COMPLIANT

11.2.5.4 Cleaning-in-place (CIP) systems, where used, shall not pose a chemical contamination risk to raw materials, ingredients, or product. CIP parameters critical to assuring effective cleaning shall be defined, monitored, and recorded (e.g., chemical and concentration used, contact time, and temperature). CIP equipment, including spray balls, shall be maintained, and any modifications to CIP equipment shall be validated. Personnel engaged in CIP activities shall be effectively trained.

RESPONSE: NOT APPLICABLE

EVIDENCE: The sites do not have a CIP system.

11.2.5.5 Cleaning equipment, tools, racks, and other items used in support of the cleaning and sanitizing program shall be clearly identified, stored, and maintained in a manner that prevents contamination of processing areas, product handling equipment, and storage areas as well as the tools themselves.

RESPONSE: COMPLIANT

11.2.5.6 Suitably equipped areas shall be designated for cleaning product containers, knives, cutting boards, and other utensils used by staff. The areas for these cleaning operations shall be controlled so they do not interfere with manufacturing operations, equipment, or product. Racks and containers for storing cleaned utensils shall be provided as required.

RESPONSE: COMPLIANT

11.2.5.7 Pre-operational inspections shall be conducted following cleaning and sanitation operations to ensure food processing areas, product contact surfaces, equipment, staff amenities, sanitary facilities, and other essential areas are clean before the start of production. Pre-operational inspections shall be conducted by qualified personnel.

RESPONSE: COMPLIANT

11.2.5.8 Staff amenities, sanitary facilities, and other essential areas shall be inspected by qualified personnel at a defined frequency to ensure the areas are clean.

RESPONSE: COMPLIANT

11.2.5.9 The responsibility and methods used to verify the effectiveness of the cleaning procedures shall be documented and implemented. A verification schedule shall be prepared. A record of pre-operational hygiene inspections, cleaning and sanitation activities, and verification activities shall be maintained.

RESPONSE: COMPLIANT

11.3.1 Personnel Welfare

There were no employees observed with an obvious illness in the production areas. Temperatures are monitored and a health statement is required prior to entering the facility. Employees are trained on how to properly sneeze and what to do if there is a bodily fluid spill. Sanitation, housekeeping and supervisors are trained on how to properly clean bodily fluid spills. Spill kits are also in place. There were no employees observed with open cuts or sores. Metal detectable band aids are used in the plants. There was no evidence of eating or drinking in the production areas.

11.3.1.1 Personnel who are known to be carriers of infectious diseases that present a health risk to others through the packing or storage processes shall not engage in the processing or packing of food or enter storage areas where food is exposed. Code Amendment #1 A medical screening procedure shall be in place for all employees, visitors and contractors who handle exposed product or food contact surfaces.

RESPONSE: COMPLIANT

11.3.1.2 The site shall have measures in place to prevent contact of materials, ingredients, food packaging, food, or food contact surfaces from any bodily fluids, open wounds, coughing, sneezing, spitting, or any other means. In the event of an injury that causes the spillage of bodily fluid, a properly trained staff member shall ensure that all affected areas, including handling and processing areas, have been adequately cleaned, and that all materials and products have been quarantined and/or disposed of.

RESPONSE: COMPLIANT

11.3.1.3 Personnel with exposed cuts, sores, or lesions shall not engage in handling or processing exposed products or handling primary (food contact) packaging or touching food contact surfaces. Minor cuts or abrasions on exposed parts of the body shall be covered with a colored, metal-detectable bandage or an alternative suitable waterproof and colored dressing.

RESPONSE: COMPLIANT

11.3.2 Handwashing

Sinks were located at the entrances of the production areas. The sinks had warm water, liquid soap, single use paper towels, and waste cans. Sanitizer was also provided. Signage was posted instructing employee to wash hands. Employees were observed washing hands when entering the production areas. Hands were washed prior to using gloves.

11.3.2.1 All personnel shall have clean hands, and hands shall be washed by all staff, contractors, and visitors: i. On entering food handling or processing areas; ii. After each visit to a toilet; iii. After using a handkerchief; iv. After smoking, eating, or drinking; and v. After handling wash down hoses, cleaning materials, dropped product, or contaminated material.

RESPONSE: COMPLIANT

11.3.2.2 Handwashing stations shall be provided adjacent to all personnel access points and in accessible locations throughout food handling and processing areas as required.

RESPONSE: COMPLIANT

11.3.2.3 Handwashing stations shall be constructed of stainless steel or similar non-corrosive material and at a minimum supplied with: i. A potable water supply at an appropriate temperature; ii. Liquid soap contained within a fixed dispenser; iii. Paper towels in a hands-free cleanable dispenser; and iv. A means of containing used paper towels.

RESPONSE: COMPLIANT

11.3.2.4 The following additional facilities shall be provided in high-risk areas: i. Hands-free operated taps; and ii. Hand sanitizers.

RESPONSE: COMPLIANT

11.3.2.5 Signage in appropriate languages instructing people to wash their hands before entering the food processing areas shall be provided in a prominent position in break rooms, at break room exits, toilet rooms, and in outside eating areas, as applicable.

RESPONSE: COMPLIANT

11.3.2.6 When gloves are used, personnel shall maintain the handwashing practices outlined above.

RESPONSE: COMPLIANT

11.3.3 Clothing and Personal Effects

A risk analysis was conducted on Dec. 18, 2019, on clothing and the hair policy. The risk analysis showed that the clothing and hair policy did not pose a threat to products. The risk assessment was reviewed during the annual review with no changes. Smocks worn by employees are stored in separate areas. Clothing and shoes were clean at the start of the shift. Extra smocks are available should they become soiled. Disposable gloves were observed being changed after breaks. Protective clothing was manufactured from appropriate materials. Racks were provided for protective clothing. There were no employees observed wearing jewelry or loose objects above the waist.

11.3.3.1 The site shall undertake a risk analysis to ensure that the clothing and hair policy protects materials, food, and food contact surfaces from unintentional microbiological or physical contamination.

RESPONSE: COMPLIANT

11.3.3.2 Clothing worn by staff engaged in handling food shall be maintained, stored, laundered, and worn so it does not present a contamination risk to products.

RESPONSE: COMPLIANT

11.3.3.3 Clothing, including shoes, shall be clean at the start of each shift and maintained in a serviceable condition.

RESPONSE: COMPLIANT

11.3.3.4 Excessively soiled uniforms shall be changed or replaced when they present a product contamination risk.

RESPONSE: COMPLIANT

11.3.3.5 Disposable gloves and aprons shall be changed after each break, upon re-entry into the processing area, and when damaged. Non-disposable aprons and gloves shall be cleaned and sanitized as required and when not in use stored on racks provided in the processing area or in designated sealed containers in personnel lockers. They should not be placed or stored on packaging, ingredients, product, or equipment.

RESPONSE: COMPLIANT

11.3.3.6 Protective clothing shall be manufactured from material that will not pose a food safety threat and is easily cleaned. All protective clothing shall be cleaned after use, or at a frequency to control contamination, and stored in a clean and serviceable condition to prevent microbiological or cross-contact allergen contamination.

RESPONSE: COMPLIANT

11.3.3.7 Racks shall be provided for the temporary storage of protective clothing when staff leave the processing area and shall be provided nearby or adjacent to the personnel access doorways and handwashing facilities.

RESPONSE: COMPLIANT

11.3.3.8 Jewelry and other loose objects shall not be worn or taken into a food handling or processing operation or into any area where food is exposed. Wearing plain bands with no stones, prescribed medical alert bracelets, or jewelry accepted for religious or cultural reasons can be permitted, provided these items are properly covered and do not pose a food safety risk. All exceptions shall meet regulatory and customer requirements and shall be subject to a risk assessment and evidence of ongoing risk management.

RESPONSE: COMPLIANT

11.3.4 Visitors

Visitors are trained on the GMP's prior to entering the processing areas. Visitors and management were observed wearing proper clothing. Everyone is required to remove jewelry and loose objects above the waist. Anyone with an obvious illness is not allowed into the facilities. Everyone must enter and exit through the proper doorways. Visitors are trained in the GMP's prior to entering the processing areas.

11.3.4.1 All visitors shall be trained in the site's food safety and hygiene procedures before entering any food processing and handling areas or shall be escorted at all times in food processing, handling, and storage areas.

RESPONSE: COMPLIANT

11.3.4.2 All visitors, including management staff, shall be required to remove jewelry and other loose objects in accordance with the facilities Good Manufacturing Practices and 11.3.3.8. All visitors shall wear suitable clothing and footwear when entering any food processing and handling area.

RESPONSE: COMPLIANT

11.3.4.3 Visitors exhibiting visible signs of illness shall be prevented from entering areas in which food is handled and processed.

RESPONSE: COMPLIANT

11.3.4.4 Visitors shall enter and exit food handling areas through the proper staff entrance points and comply with all handwashing and personnel practice requirements.

RESPONSE: COMPLIANT

11.3.5 Staff Amenities (change rooms, toilet, break rooms)

Employee amenities are cleaned daily and were available to all employees. Change rooms are not provided. This is not a high risk processor. Racks are provided for employees to store coats. Showers are not provided or required. Restrooms located in the plants are away from the production areas. The restrooms are accessible through an adjoining room. The areas were clean and well maintained. Hooks are available for storing smocks. Sanitary drainage is connected directly to the sewage system. Sinks are provided in the restrooms and are constructed as outlined in 11.3.2.3. The lunch rooms in the plants are located by the main employee entrances. The lunch rooms were well ventilated, clean, had microwaves, refrigeration, and a sink. The areas were clean. The outside eating areas were clean and free from waste.

11.3.5.1 Staff amenities shall have documented cleaning procedures, be supplied with appropriate lighting and ventilation, and shall be made available for use by all persons engaged in the handling and processing of product.

RESPONSE: COMPLIANT

11.3.5.2 Change rooms shall be provided to enable staff and visitors to change into and out of protective clothing as required. Change rooms shall be kept clean.

RESPONSE: NOT APPLICABLE

EVIDENCE: Change rooms are not provided.

11.3.5.3 High-risk change areas shall be provided for staff engaged in the processing of high-risk foods or processing operations in which clothing can be soiled.

RESPONSE: NOT APPLICABLE

EVIDENCE: This is not a high risk processor.

11.3.5.4 Provision shall be made for staff to store their street clothing and personal items separate from clean uniforms, food contact zones, food, and packaging storage areas.

RESPONSE: COMPLIANT

11.3.5.5 Where required, a sufficient number of showers shall be provided for use by staff.

RESPONSE: NOT APPLICABLE

EVIDENCE: Showers are not provided or required.

11.3.5.6 Toilet rooms shall be: i. Designed and constructed so that they are accessible to staff and separate from any processing and food handling operations; ii. Accessed from the processing area via an airlock vented to the exterior or through an adjoining room; iii. Sufficient in number for the maximum number of staff; iv. Constructed so that they can be easily cleaned and maintained; v. Located inside or nearby areas for storing protective clothing, outer garments, and other items while using the facilities; and vi. Kept clean and tidy. Tools/equipment used for cleaning toilet rooms shall not be used to clean processing areas.

RESPONSE: COMPLIANT

11.3.5.7 Sanitary drainage shall not be connected to any other drains within the premises and shall be directed to a septic tank or a sewerage system in accordance with regulations.

RESPONSE: COMPLIANT

11.3.5.8 Handwashing basins shall be provided immediately outside or inside the toilet room and designed as outlined in 11.3.2.3.

RESPONSE: COMPLIANT

11.3.5.9 Separate break rooms shall be provided away from food contact/handling zones. Break rooms shall be: i. Ventilated and well lit; ii. Provided with adequate tables and seating to cater for the maximum number of staff at one sitting; iii. Equipped with a sink serviced with hot and cold potable water for washing utensils; iv. Equipped with refrigeration and heating facilities, enabling staff to store or heat food and to prepare non-alcoholic beverages if required; and v. Kept clean and free from waste materials and pests.

RESPONSE: COMPLIANT

11.3.5.10 Where outside eating areas are provided, they should be kept clean and free from waste materials and maintained in a manner that minimizes the potential for the introduction of contamination, including pests to the site.

RESPONSE: COMPLIANT

11.4.1 Staff Engaged in Food Handling and Processing Operations

Employees were observed entering the processing areas through the proper doorways. Doors were closed. Ingredients and products were stored off of the floor. Employees were observed following proper GMP's. Minor - Several candy wrappers were observed in the yellow pole protectors in the warehouse area at the Elk Grove facility. The flow of employees is from open components to packaged product. No contamination issues were observed. Sensory evaluations are conducted in the kitchen area.

11.4.1.1 All personnel engaged in any food handling, preparation, or processing operations shall ensure that products and materials are handled and stored in such a way as to prevent damage or product contamination. They shall comply with the following processing practices: i. Personnel entry to processing areas shall be through the personnel access doors only; ii. All doors are to be kept closed. Doors shall not be open for extended periods when access is required for waste removal or receiving of product/ingredient/packaging; iii. Packaging, product, and ingredients shall be kept in appropriate containers as required and off the floor; iv. Waste shall be contained in the bins identified for this purpose and removed from the processing area on a regular basis and not left to accumulate; and v. All wash down and compressed air hoses shall be stored on hose racks after use and not left on the floor.

RESPONSE: COMPLIANT

11.4.1.2 Personnel working in or visiting food handling or processing operations shall ensure that: i. Staff shall not eat or taste any product being processed in the food handling/contact zones, except as noted in element 11.4.1.4; ii. The wearing of false fingernails, false eyelashes, eyelash extensions, long nails, or fingernail polish is not permitted when handling exposed food; iii. Hair restraints and beard covers, where applicable, shall be used in areas where product is exposed. iv. Smoking, chewing, eating, or spitting is not permitted in areas where product is produced, stored, or otherwise exposed. v. Drinking water is permissible only under conditions that prevent contamination or other food safety risks from occurring. Drinking water containers in production and storage areas shall be stored in clear, covered containers, and in designated areas away from raw materials, packaging, tools, or equipment storage.

RESPONSE: MINOR

EVIDENCE: Several candy wrappers were observed in the yellow pole protectors in the warehouse area at the Elk Grove facility.

ROOT CAUSE: Employees are trained upon hire that no eating is to be done in non-designated areas. Warehouse personnel needed to be reminded of proceudre.

CORRECTIVE ACTION: Candy wrappers were removed during the audit. Warehouse personnal received a re-training about posted GMPs and that eating can only be done designated areas.

VERIFICATION OF CLOSEOUT: Reviewed the training record and approved the corrective action.

COMPLETION DATE: 02/16/2022 **CLOSEOUT DATE:** 02/24/2022

11.4.1.3 The flow of personnel in food processing and handling areas shall be managed such that the potential for contamination is minimized.

RESPONSE: COMPLIANT

11.4.1.4 In circumstances where it is necessary to undertake sensory evaluations in a food handling/contact zone, the site shall implement controls and procedures to ensure: i. Food safety is not compromised; ii. Sensory evaluations are conducted by authorized personnel only; iii. A high standard of personal hygiene is practiced by personnel conducting sensory evaluations; iv. Sensory evaluations are conducted in areas equipped for the purpose; and v. Equipment used for sensory evaluations is sanitized, maintained, and stored separately from processing equipment.

RESPONSE: COMPLIANT

11.5.1 Water Supply

Only potable water was used in the facilities. There was an adequate amount of water available for cleaning. The sites use a minimal amount of water for sanitation. How loss of water is handled is part of the Business Continuity plan. The backflows were last tested in Mar. 21, 2021. Non-potable water was not used in the plants. Water was not stored at the plants.

11.5.1.1 Adequate supplies of potable water drawn from a known clean source shall be provided for water used as an ingredient during processing operations and for cleaning the premises and equipment. The source of potable water shall be identified as well as on-site storage (if applicable) and reticulation within the facility.

RESPONSE: COMPLIANT

11.5.1.2 Contingency plans shall be in place for instances when the potable water supply is deemed to be contaminated or otherwise inappropriate for use.

RESPONSE: COMPLIANT

11.5.1.3 Supplies of hot and cold water shall be provided, as required, to enable the effective cleaning of the premises and equipment.

RESPONSE: COMPLIANT

11.5.1.4 The delivery of water within the premises shall ensure potable water is not contaminated. Testing of the backflow system, where possible, shall be conducted at least annually and records shall be maintained.

RESPONSE: COMPLIANT

11.5.1.5 The use of non-potable water shall be controlled such that: i. There is no cross-contamination between potable and non-potable water lines; ii. Non-potable water piping and outlets are clearly identified; and iii. Hoses, taps, and other similar sources of possible contamination are designed to prevent backflow or back-siphonage.

RESPONSE: NOT APPLICABLE

EVIDENCE: Non-potable water was not used in the plant.

11.5.1.6 Where water is stored on-site, storage facilities shall be adequately designed, constructed, and routinely cleaned to prevent contamination.

RESPONSE: NOT APPLICABLE

EVIDENCE: Water was not stored at the plants.

11.5.2 Water Treatment

Water treatment is not conducted.

11.5.2.1 Water treatment methods, equipment, and materials, if required, shall be designed, installed, and operated to ensure water receives effective treatment. Water treatment equipment shall be monitored regularly to ensure it remains serviceable.

RESPONSE: NOT APPLICABLE

11.5.2.2 Water used as an ingredient in processing or for cleaning and sanitizing equipment shall be tested and, if required, treated to maintain potability (refer to 11.5.2.1).

RESPONSE: NOT APPLICABLE

11.5.2.3 Treated water shall be regularly monitored to ensure it meets the specified indicators. Water treatment chemicals usage shall be monitored to ensure chemical residues are within acceptable limits. Records of testing results shall be kept.

RESPONSE: NOT APPLICABLE

11.5.3 Water Quality

The water reports reviewed for Elk Grove Village, Bensenville, and Bartlett for 2021, showed that the water used met national quality requirements. Water was tested at all three sites on between May 7 and 15, 2021. The results for Coliform were <1.1 MNP/100 ml. using test method SMEWW 22nd Ed. 9221E.

11.5.3.1 Water shall comply with local, national, or internationally recognized potable water microbiological and quality standards, as required when used for: i. Washing, thawing, and treating food; ii. Handwashing; iii. Conveying food; iv. An ingredient or food processing aid; v. Cleaning food contact surfaces and equipment; vi. The manufacture of ice; or vii. The manufacture of steam that will come into contact with food or be used to heat water that will come into contact with food.

RESPONSE: COMPLIANT

11.5.3.2 Microbiological analysis of the water and ice supply shall be conducted to verify the cleanliness of the supply, the monitoring activities, and the effectiveness of the treatment measures implemented. Samples for analysis shall be taken at sources supplying water for the process or cleaning or from within the site. The frequency of analysis shall be risk-based and at a minimum annually.

RESPONSE: COMPLIANT

11.5.3.3 Water and ice shall be analyzed using reference standards and methods.

RESPONSE: COMPLIANT

11.5.4 Ice Supply

Ice is not used in the process.

11.5.4.1 Ice provided for use during processing operations, as a processing aid, or an ingredient shall comply with 11.5.3.1.

RESPONSE: NOT APPLICABLE

11.5.4.2 Ice that is purchased shall be from an approved supplier and included in the site's food safety risk assessment. Ice shall be supplied in containers that are appropriate for use, cleanable if reused, and tested as appropriate.

RESPONSE: NOT APPLICABLE

11.5.4.3 Ice rooms and receptacles shall be constructed of materials as outlined in element 11.1.2 and designed to minimize contamination of the ice during storage, retrieval, and distribution.

RESPONSE: NOT APPLICABLE

11.5.5 Air and Other Gasses

Compressed air is filtered with .01 mm micron filters. The filters are included on the PM schedule. Compressed air is tested monthly for APC. The APC results were reviewed for Jan. 11, 2022. The results were in specification.

11.5.5.1 Compressed air or other gases (e.g., nitrogen or carbon dioxide) that contact food or food contact surfaces shall be clean and present no risk to food safety.

RESPONSE: COMPLIANT

11.5.5.2 Compressed air systems and systems used to store or dispense other gases that come into contact with food or food contact surfaces shall be maintained and regularly monitored for quality and applicable food safety hazards. The frequency of analysis shall be risk-based and at a minimum annually.

RESPONSE: COMPLIANT

11.6.1 Receipt, Storage and Handling of Goods

Components and ingredients are received in SyteLine. A license plate is issued and the item is assigned an area to be stored in. Stock rotation is based on First Expired First Out. Inventories are maintained in SyteLine to ensure that components are used before the expiration dates. No expired products or ingredients were observed. Alterative storage was not used.

11.6.1.1 The site shall document and implement an effective storage plan that allows for the safe, hygienic receipt and storage of raw materials (i.e., frozen, chilled, and ambient), ingredients, packaging, equipment, and chemicals.

RESPONSE: COMPLIANT

11.6.1.2 Controls shall be in place to ensure all ingredients, raw materials, processing aids, and packaging are received and stored properly to prevent cross-contamination risks. Unprocessed raw materials shall be received and stored separately from processed raw materials to avoid cross-contamination risk.

RESPONSE: COMPLIANT

11.6.1.3 The responsibility and methods for ensuring effective stock rotation principles shall be documented and implemented.

RESPONSE: COMPLIANT

11.6.1.4 Procedures shall be in place to ensure that all ingredients, materials, work- in-progress, rework, and finished product are utilized within their designated shelf-life.

RESPONSE: COMPLIANT

11.6.1.5 Where raw materials, ingredients, packaging, equipment, and chemicals are held under temporary or overflow conditions that are not designed for the safe storage of goods, a risk analysis shall be undertaken to ensure there are no risks to the integrity of those goods, no potential for contamination or adverse effect on food safety.

RESPONSE: NOT APPLICABLE

EVIDENCE: Alterative storage was not used.

11.6.1.6 Records shall be available to verify the effectiveness of alternate or temporary control measures for the storage of raw materials, ingredients, packaging, equipment, chemicals, or finished products.

RESPONSE: NOT APPLICABLE

EVIDENCE: Alterative storage was not used.

11.6.2 Cold Storage, Freezing and Chilling of Foods

The site does not have freezers or coolers.

11.6.2.1 The site shall provide confirmation of the effective operational performance of freezing, chilling, and cold storage facilities. Chillers, blast freezers, and cold storage rooms shall be designed and constructed to allow for the hygienic and efficient refrigeration of food and be easily accessible for inspection and cleaning.

RESPONSE: NOT APPLICABLE

11.6.2.2 Sufficient refrigeration capacity shall be available to chill, freeze, store chilled, or store frozen the maximum anticipated throughput of product with allowance for periodic cleaning of refrigerated areas.

RESPONSE: NOT APPLICABLE

11.6.2.3 The site shall have a written procedure for monitoring temperatures, including the frequency of checks, and corrective actions, if the temperature is out of specification. Freezing, chilling, and cold storage rooms shall be fitted with temperature monitoring equipment that is located to monitor the warmest part of the room and be fitted with a temperature measurement device that is easily readable and accessible. Records shall be kept of frozen, cold, and chilled storage room temperatures.

RESPONSE: NOT APPLICABLE

11.6.2.4 Discharge from defrost and condensate lines shall be controlled and discharged into the drainage system.

RESPONSE: NOT APPLICABLE

11.6.3 Storage of Dry Ingredients, Packaging, and Shelf Stable Packaged Goods

Storage areas were in overall good condition. No harborage areas were observed. Racks were in good condition. The areas are cleaned on a defined frequency.

11.6.3.1 Rooms used for the storage of product ingredients, packaging, and other dry goods shall be located away from wet areas and constructed to protect the product from contamination and deterioration and prevent packaging from becoming a harborage for pests or vermin.

RESPONSE: COMPLIANT

11.6.3.2 Racks provided for the storage of packaging shall be constructed of impervious materials and designed to enable cleaning and inspection of the floors and behind the racks. Storage areas shall be cleaned at a pre-determined frequency.

RESPONSE: COMPLIANT

11.6.4 Storage of Hazardous Chemicals and Toxic Substances

Chemicals in the facilities are stored in storage areas. The storage areas are locked and marked as a chemical storage area. A register of chemicals is maintained along with the SDS sheets. Processing utensils and packaging materials were not stored in the chemical storage areas. Pesticide chemicals were not stored on sites. Chemicals were labeled and not store by the lines. Chemicals were restricted to authorized employees only. Employees are trained in chemical handling and are provided with protective equipment when required. Empty chemical containers are triple rinsed and recycled. Large containers are recycled by the chemical company. Spill equipment was in place.

11.6.4.1 Hazardous chemicals and toxic substances with the potential for food contamination shall be: i. Clearly labeled, identifying and matching the contents of their containers; ii. Included in a current register of all hazardous chemicals and toxic substances that are stored on-site; and iii. Supplemented with current Safety Data Sheets (SDS) made available to all staff.

RESPONSE: COMPLIANT

11.6.4.2 Storage of hazardous chemicals and toxic substances shall be: i. Located in an area with appropriate signage indicating that the area is for hazardous storage; ii. Controlled, lockable, and accessible only by personnel trained in the storage and use of chemicals; iii. Adequately ventilated; iv. Stored where intended and not comingled (e.g., food versus non-food grade); v. Designed such that pesticides, rodenticides, fumigants, and insecticides are stored separately from sanitizers and detergents; and vi. Stored in a manner that prevents a hazard to finished product or product contact surfaces. Processing utensils and packaging shall not be stored in areas used to store hazardous chemicals and toxic substances.

RESPONSE: COMPLIANT

11.6.4.3 Hazardous chemicals and toxic substances shall be correctly labeled and: i. Used only according to manufacturers' instructions; ii. Controlled to prevent contamination or a hazard to raw and packaging material, work-inprogress, finished product, or product contact surfaces; iii. Returned to the appropriate storage areas after use; and iv. Be compliant with national and local legislation.

RESPONSE: COMPLIANT

11.6.4.4 Daily supplies of chemicals used for continuous sanitizing of water, as a processing aid, or for emergency cleaning of food processing equipment and surfaces in food contact zones may be stored within or in close proximity to a processing area, provided that access to the chemical storage facility is restricted to only authorized personnel.

RESPONSE: COMPLIANT

11.6.4.5 Personnel who handle hazardous chemicals and toxic substances, including pesticides and cleaning chemicals,: i. Shall be fully trained in the purpose of the hazardous chemicals and toxic substances, their storage, handling, and use; ii. Be provided first aid equipment and personnel protective equipment (PPE); and iii. Ensure compliance with the proper identification, storage, usage, disposal, and clean-up requirements.

RESPONSE: COMPLIANT

11.6.4.6 The site shall dispose of empty, obsolete, and unused chemicals, pesticides, toxic substances, and containers in accordance with requirements and ensure that primary containers are: i. Not reused; ii. Segregated and securely stored prior to collection; and iii. Disposed through an approved vendor.

RESPONSE: COMPLIANT

11.6.4.7 In the event of a hazardous spill, the site shall: i. Have spillage clean-up instructions to ensure that the spill is properly contained; and ii. Be equipped with PPE, spillage kits, and cleaning equipment.

RESPONSE: COMPLIANT

11.6.5 Loading, Transport, and Unloading Practices

Receiving and Shipping Instructions are in place. The instructions were up dated on May 21, 2019. Shipping and receiving is conducted at different doors. No cross contamination was observed. Trailers are inspected prior to loading and unloading. Trailers are checked for cleanliness, odors and trailer condition. Vehicles used for shipping are sealed after loading. Loading and unloading docks were in good condition and clean. The site does not ship refrigerated products. The site does not receive refrigerated items. Unloading practices were from dock doors. No product contamination was observed.

11.6.5.1 The practices applied during loading, transport, and unloading of food shall be documented, implemented, and designed to maintain appropriate storage conditions and product integrity. Foods shall be loaded, transported, and unloaded under conditions suitable to prevent cross-contamination.

RESPONSE: COMPLIANT

11.6.5.2 Vehicles (e.g., trucks/vans/containers) used for transporting food within the site and from the site shall be inspected prior to loading to ensure they are clean, in good repair, suitable for the purpose, and free from odors or other conditions that may impact negatively on the product.

RESPONSE: COMPLIANT

11.6.5.3 Vehicles (e.g., trucks/vans/containers) shall be secured from tampering using seals or other agreed-upon and acceptable devices or systems.

RESPONSE: COMPLIANT

11.6.5.4 Loading and unloading docks shall be designed to protect the product during loading and unloading. Loading practices shall be designed to minimize unnecessary exposure of the product to conditions detrimental to maintaining product and package integrity during loading and transport.

RESPONSE: COMPLIANT

11.6.5.5 Refrigerated units shall maintain the product at the required temperature. The unit's temperature settings shall be set, checked, and recorded before loading, and the product temperature shall be recorded at regular intervals during loading, as applicable.

RESPONSE: NOT APPLICABLE

EVIDENCE: The site does not ship refrigerated products.

11.6.5.6 The refrigeration unit shall be operational at all times and checks completed of the unit's operation, the door seals, and the storage temperature at regular intervals during transit.

RESPONSE: NOT APPLICABLE

EVIDENCE: The site does not ship refrigerated products.

11.6.5.7 On arrival, prior to opening the doors, the food transport vehicle's refrigeration unit's storage temperature settings and operating temperature shall be checked and recorded. Unloading shall be completed efficiently, and product temperatures shall be recorded at the start of unloading and regular intervals during unloading.

RESPONSE: NOT APPLICABLE

EVIDENCE: The site does not receive refrigerated items.

11.6.5.8 Unloading practices shall be designed to minimize unnecessary exposure of the product to conditions detrimental to maintaining product and package integrity.

RESPONSE: COMPLIANT

11.7.1 High-Risk Processes

This is not a high risk processor.

11.7.1.1 The processing of high-risk food shall be conducted under controlled conditions, such that sensitive areas, in which the high-risk food has undergone a "kill" step, a "food safety intervention" or is subject to post-process handling, are protected/segregated from other processes, raw materials, or staff who handle raw materials, to ensure cross-contamination is minimized.

RESPONSE: NOT APPLICABLE

11.7.1.2 Ambient air in high-risk areas shall be tested at least annually to confirm that it does not pose a risk to food safety.

RESPONSE: NOT APPLICABLE

11.7.1.3 Areas in which high-risk processes are conducted shall only be serviced by staff dedicated to that function.

RESPONSE: NOT APPLICABLE

11.7.1.4 Staff engaged in high-risk areas shall change into clean clothing and footwear or temporary protective outerwear when entering high-risk areas. Staff access points shall be located, designed, and equipped to enable staff to change into the distinctive protective clothing and practice a high standard of personal hygiene to prevent product contamination.

RESPONSE: NOT APPLICABLE

11.7.1.5 Product transfer points shall be located and designed, so they do not compromise high-risk segregation and minimize the risk of cross-contamination.

RESPONSE: NOT APPLICABLE

11.7.2 Thawing of Food

Thawing is not conducted.

11.7.2.1 Thawing of food shall be undertaken in equipment and rooms appropriate for the purpose. Equipment for water thawing shall be continuous flow to ensure the water exchange rate and temperature do not contribute to product deterioration or contamination. Water overflow shall be directed into the floor drainage system and not onto the floor or shall be appropriately plumbed.

RESPONSE: NOT APPLICABLE

11.7.2.2 Air thawing facilities shall be designed to thaw food under controlled conditions at a rate and temperature that does not contribute to product deterioration or contamination.

RESPONSE: NOT APPLICABLE

11.7.2.3 Provision is to be made for the containment and regular disposal of used cartons and packaging from thawed product so that there is no risk to the product.

RESPONSE: NOT APPLICABLE

11.7.3 Control of Foreign Matter Contamination

A Foreign Material policy is in place. The policy was updated on Jul. 7, 2021. All employees are responsible for foreign material control. Monthly and daily inspections are conducted to ensure the plants and equipment remain in good condition. There were no glass or ceramic items in the processing areas. Glass and brittle plastic registers are in place for all plants. The registers were updated on Nov. 2021. The registers were complete for the items reviewed during the audit. Daily and monthly inspections are conducted of the processing areas. There are no glass instruments and MIG thermometers in the processing areas. Wooden pallets were in good condition. There were no loose metal objects on or over equipment. Knives are controlled and were clean. The site does not have rubber gaskets or other equipment that can wear out.

11.7.3.1 The responsibility and methods used to prevent foreign matter contamination of the product shall be documented, implemented, and communicated to all staff. Inspections shall be performed (refer to 2.5.4.3) to ensure plant and equipment remain in good condition and equipment has not become detached or deteriorated and is free from potential contaminants.

RESPONSE: COMPLIANT

11.7.3.2 Containers, equipment, and other utensils made of glass, porcelain, ceramics, laboratory glassware, or other similar materials shall not be permitted in food processing /contact zones (except where the product is contained in packaging made from these materials, or measurement instruments with glass dial covers are used, or MIG thermometers are required under regulation). Where glass objects or similar material are required in food handling/contact zones, they shall be listed in a glass inventory, including details of their location and condition.

RESPONSE: COMPLIANT

EVIDENCE: The registers were updated in Nov. 2021.

11.7.3.3 Regular inspections of food handling/contact zones shall be conducted (refer to 2.5.4.3) to ensure they are free of glass or other like material and to establish changes to the condition of the objects listed in the glass inventory.

RESPONSE: COMPLIANT

11.7.3.4 Glass instrument dial covers on processing equipment and MIG thermometers shall be inspected at the start of each shift to confirm they have not been damaged.

RESPONSE: NOT APPLICABLE

EVIDENCE: There are no glass instruments and MIG thermometers in the processing areas

11.7.3.5 In circumstances where glass or similar material breakage occurs, the affected area shall be isolated, cleaned, thoroughly inspected (including cleaning equipment and footwear), and cleared by a suitably responsible person prior to the start of operations.

RESPONSE: COMPLIANT

11.7.3.6 Wooden pallets and other wooden utensils used in food processing and handling areas shall be dedicated for that purpose, clean, and maintained in good order. Their condition shall be subject to regular inspection.

RESPONSE: COMPLIANT

11.7.3.7 Loose metal objects on equipment, equipment covers, and overhead structures shall be removed or tightly fixed so as not to present a hazard.

RESPONSE: COMPLIANT

11.7.3.8 Knives and cutting instruments used in processing and packaging operations shall be controlled, kept clean, and well maintained. Snap-off blades shall not be used in manufacturing or storage areas.

RESPONSE: COMPLIANT

11.7.3.9 Gaskets, rubber impellers, and other equipment made of materials that can wear or deteriorate over time shall be inspected on a regular frequency (refer to 2.5.4.3).

RESPONSE: NOT APPLICABLE

EVIDENCE: The site does not have rubber gaskets or other equipment that can wear out.

11.7.4 Detection of Foreign Objects

There are no screens or filters in the production areas. The metal detectors/x-rays are challenged with .8 mm to 2.5 mm Fe, .8 mm to 2.5 mm non-Fe, and 1.0mm to 2.5 mm stainless steel wands. The metal detectors are challenged at the start of the shift every two hours and end of production. The metal detectors/x-rays challenged during the audit were working properly. In case of foreign material contamination, the batch is isolated and inspected. The batch is either reworked or disposed off.

11.7.4.1 The responsibility, methods, and frequency for monitoring, maintaining, calibrating, and using screens, sieves, filters, or other technologies to remove or detect foreign matter shall be documented and implemented.

RESPONSE: COMPLIANT

11.7.4.2 Where detection and/or removal systems are used, the site shall establish limits for detection, based on a risk assessment of the product and its packaging, and identify the location(s) of the detector(s) in the process.

RESPONSE: COMPLIANT

11.7.4.3 Metal detectors or other physical contaminant detection technologies shall be routinely monitored, validated, and verified for operational effectiveness. The equipment shall be designed to isolate defective product and indicate when it is rejected.

RESPONSE: COMPLIANT

11.7.4.4 Records shall be maintained of the inspection of foreign object detection devices, of any products rejected or removed by them, and of corrective and preventative actions resulting from the inspections.

RESPONSE: COMPLIANT

11.7.4.5 In all cases of foreign matter contamination, the affected batch or item shall be isolated, inspected, reworked, or disposed of. Records shall be maintained of the disposition.

RESPONSE: COMPLIANT

11.8.1 Waste Disposal

A Waste Management policy is in place. The policy was updated on Apr. 5, 2019. Waste was contained in bins and stored in designated areas. The waste was removed at regular intervals. The site does not have waste or overflow water from tubs or equipment. Waste disposal bins were in good condition and color coded. Solid processing waste is stored in designated areas. Trademarked material disposal is tracked with a certificate of destruction. Waste held for animal feed is stored in black stretch wrapped totes. The waste collection area was clean. The site has no liquid waste. Reviews of waste management is conducted during each shift by QA.

11.8.1.1 The responsibility and methods used to collect and handle dry, wet, and liquid waste and how to store it prior to removal from the premises shall be documented and implemented.

RESPONSE: COMPLIANT

11.8.1.2 Waste shall be removed on a regular basis and not allowed to build up in food handling or processing areas. Designated waste accumulation areas shall be maintained in a clean and tidy condition until external waste collection is undertaken.

RESPONSE: COMPLIANT

11.8.1.3 Waste and overflow water from tubs, tanks, and other equipment shall be discharged directly to the floor drainage system or by an alternative method that meets local regulatory requirements.

RESPONSE: NOT APPLICABLE

EVIDENCE: The site does not have waste or overflow water from tubs or equipment.

11.8.1.4 Trolleys, vehicle waste disposal equipment, collection bins, and storage areas shall be maintained in a serviceable condition, cleaned, and sanitized regularly to prevent the attraction of pests and other vermin.

RESPONSE: COMPLIANT

11.8.1.5 Adequate provision shall be made for the disposal of all solid processing waste, including trimmings, inedible material, and used packaging.

RESPONSE: COMPLIANT

11.8.1.6 Where applicable, a documented procedure shall be in place for the controlled disposal of trademarked materials waste considered high-risk for handling or other reasons. Where a contracted disposal service is used, the disposal process shall be reviewed regularly to confirm compliance.

RESPONSE: COMPLIANT

11.8.1.7 Inedible waste designated for animal feed shall be stored and handled so that it will not cause a risk to the animal or further processing. If denaturant is used to identify inedible waste, it shall be demonstrated that it does not pose a risk to animal health.

RESPONSE: COMPLIANT

11.8.1.8 Waste held on-site prior to disposal shall be stored in a separate storage facility that is suitably insect proofed and located where it does not present any hazards.

RESPONSE: COMPLIANT

11.8.1.9 Adequate provision shall be made for the disposal of all liquid waste from processing and food handling areas. Liquid waste shall either be removed from the processing environment continuously or held in a designated storage area in lidded containers prior to disposal where it does not present any hazards.

RESPONSE: NOT APPLICABLE

EVIDENCE: The site has no liquid waste.

11.8.1.10 Reviews of the effectiveness of waste management shall form part of regular site inspections (refer to 2.5.4.3), and the results of these inspections shall be included in the relevant inspection reports.

RESPONSE: COMPLIANT

13.1.1 Premises Location and Approval

The site is located in an industrial area. The exterior of the site is monitored during the monthly audits. The site is registered with the FDA. The registration expires on Dec. 31, 2022.

13.1.1.1 The site shall assess local activities and the site environment to identify any risks that may have an adverse impact on product safety and implement controls for any identified risks. The assessment shall be reviewed in response to any changes in the local environment or activities. The construction and ongoing operation of the premises on the site shall be approved by the relevant authority.

RESPONSE: COMPLIANT

13.1.2 Building Materials

Floors were in overall good condition. The site does not have drains on the production floor. The site does not have waste traps. Walls, ceilings and doors were in good condition and of solid construction. Wall to wall and floor to wall junctions were in good condition. Doors were of solid construction. Windows were made of shatterproof material.

13.1.2.1 Floors shall be constructed of smooth, dense, impact-resistant material that can be effectively graded, drained, are impervious to liquid, and easily cleaned.

RESPONSE: COMPLIANT

13.1.2.2 Drains shall be constructed and located so they can be easily cleaned and do not present a food safety hazard.

RESPONSE: NOT APPLICABLE

EVIDENCE: The site does not have drains on the production floor.

13.1.2.3 Waste trap system shall be located sufficiently far away from any food sector packaging handling area or entrance to the premises to prevent contamination.

RESPONSE: NOT APPLICABLE

EVIDENCE: The site does not have waste traps.

13.1.2.4 Walls, partitions, ceilings, and doors shall be of durable construction.

RESPONSE: COMPLIANT

13.1.2.5 In food sector packaging manufacturing, handling, and storage areas, wall-to-wall and wall-to-floor junctions shall be designed to be easily cleaned and sealed to prevent the accumulation of debris.

RESPONSE: COMPLIANT

13.1.2.6 In food sector packaging manufacturing, handling, and storage areas, doors shall be of solid construction and windows shall be of shatterproof glass or similar material.

RESPONSE: COMPLIANT

13.1.3 Lightings and Light Fittings

There was sufficient amount of lighting in the facility. The lighting was shielded with shatterproof covers. Light shields in the warehouse areas were shielded.

13.1.3.1 Lighting in food sector packaging manufacturing, handling, and storage areas shall be of appropriate intensity to enable the staff to carry out their tasks efficiently and effectively.

RESPONSE: COMPLIANT

13.1.3.2 Light fittings in food sector packaging manufacturing, handling, and storage areas shall be shatterproof, manufactured with a shatterproof covering, or fitted with protective covers and recessed into or fitted flush with the ceiling. Where fixtures cannot be recessed, structures shall be protected from accidental breakage, manufactured from cleanable materials, and included in the cleaning and sanitation program.

RESPONSE: COMPLIANT

13.1.3.3 Light fittings in areas where the product is stored shall be designed to prevent product contamination.

RESPONSE: COMPLIANT

13.1.4 Dust, Insect, and Pest Proofing

External doors and windows were sealed. A dust system is in place to help eliminate dust in the processing area. Personnel access doors are self-closing. There was an adequate amount of sealing around trailers. External doors are self closing. Electric insect devices are located away from product. No bait was used on the interior of the plant.

13.1.4.1 All external windows, ventilation openings, doors, and other openings shall be effectively sealed when closed and proofed against dust, vermin, and other pests. External personnel access doors shall be effectively insect-proofed and fitted with a self-closing device and proper seals to protect against entry of dust, vermin, and other pests.

RESPONSE: COMPLIANT

13.1.4.2 Methods shall be in place to adequately control dust that may result from the manufacturing process.

RESPONSE: COMPLIANT

13.1.4.3 External access doors and overhead dock doors used for product, material, pedestrian, or vehicle access shall be effectively designed, maintained, and fitted with proper seals to protect against entry of dust, vermin, and other pests.

RESPONSE: COMPLIANT

13.1.4.4 Electric insect control devices, pheromone, or other traps and baits shall be located so as not to present a contamination risk to food sector packaging or manufacturing equipment. Poison rodenticide bait shall not be used inside food sector packaging manufacturing, handling, or storage areas.

RESPONSE: COMPLIANT

13.1.5 Ventilation

There was an adequate amount of ventilation in the facility. Minor - Several fans by the lines in the blow molding area (Bartlett) had dust build up.

13.1.5.1 Adequate ventilation shall be provided in enclosed packaging manufacture and handling areas.

RESPONSE: MINOR

EVIDENCE: Several fans by the lines in the blow molding area (Bartlett) had dust build up.

ROOT CAUSE: Fans were not included in the weekly cleaning checklist.

CORRECTIVE ACTION: Fans were added to the weekly cleaning checklist for Blow Molding and Winding

VERIFICATION OF CLOSEOUT: Reviewed the new MS schedule and approved the corrective action.

COMPLETION DATE: 02/18/2022 **CLOSEOUT DATE:** 02/24/2024

13.1.6 Equipment and Utensils

Specifications are in place for equipment and clothing. All new equipment purchased must be cleanable and of sanitary design. Equipment and utensils were installed to allow for cleaning. The equipment and utensils were in overall good condition. Forklifts were in good condition and did not pose a hazard to product. Non-conforming equipment is tagged. Disposal of equipment will be documented. Product contact surfaces were in good condition and constructed from materials suitable for the industry.

13.1.6.1 Specifications for new equipment and procedures for purchasing equipment to ensure it is appropriate for the task shall be documented and implemented.

RESPONSE: COMPLIANT

13.1.6.2 Equipment shall be designed, constructed, installed, operated, and maintained so as not to pose a contamination threat to food sector packaging and to allow for cleaning beneath and behind it. Tools, utensils, and containers used for handling raw materials or packaging, work-in-progress, and food sector packaging shall be made of foodsafe materials.

RESPONSE: COMPLIANT

13.1.6.3 Vehicles used in food sector packaging manufacturing, handling, or storage areas shall be designed and operated so as not to present a food safety hazard.

RESPONSE: COMPLIANT

13.1.6.4 Non-conforming equipment shall be identified, tagged, and segregated for repair or disposal in a manner that minimizes the risk of inadvertent use, improper use, or risk to the integrity of finished product. Records of the handling, corrective action, and/or disposal of non-conforming equipment shall be maintained.

RESPONSE: COMPLIANT

13.1.6.5 In sites where food sector packaging is manufactured, product contact surfaces shall be constructed of materials that will not contribute to a food safety risk to the manufacture of packaging materials.

RESPONSE: COMPLIANT

13.1.7 Grounds and Roadways

The exterior of the facility was in good condition. To waste accumulation was observed. Paths and roadways were in good condition and paved. No pooling water was observed.

13.1.7.1 The external grounds and areas surrounding the premises, including external storage buildings, machinery, and equipment shall be maintained to prevent accumulated debris and waste and control vegetation. These areas shall be inspected routinely to ensure they will not attract pests and vermin or present a food safety hazard to the sanitary operation of the site.

RESPONSE: COMPLIANT

13.1.7.2 Paths, roadways, and loading and unloading areas shall be maintained so as not to present a food safety hazard to the operation of the premises. They shall be adequately drained to prevent pooling of water. Drains shall be separate from the site drainage system and regularly cleared of debris.

RESPONSE: COMPLIANT

13.2.1 Repairs and Maintenance

A Preventative Maintenance Program is in place. The Preventative Maintenance Schedule is maintained in CMMS. The PM's cover all areas of the facilities. Weekly work orders are generated and then completed during the week. The completed work orders are documented in CMMS. Records reviewed for Dec. 2021 were complete. Failures of plant equipment are documented and are used to adjust the PM schedule if required. Supervisors are notified when maintenance is to be completed in their area. If maintenance will impact product, the line is shut down and repairs are completed after production. If temporary repairs are used the work order can be marked as waiting for parts. When the part is received and the work completed, the work order is closed out. Only food grade lubricants were used in the processing areas. The food grade lubricants were stored separate from non-food grade lubricants. Paint was not observed on product contact zones.

13.2.1.1 The methods and responsibility for the maintenance and repair of the facility, equipment, and buildings shall be documented, planned, and implemented in a manner that minimizes the risk of contamination of food sector packaging material or equipment.

RESPONSE: COMPLIANT

13.2.1.2 Routine maintenance of the equipment in any food sector packaging manufacturing, handling, or storage area shall be performed according to a maintenance control schedule and recorded. The maintenance schedule shall include the building, equipment, vehicles, and other areas of the premises critical to the maintenance of food safety.

RESPONSE: COMPLIANT

13.2.1.3 Equipment failures shall be documented, and repair activities shall be incorporated into the maintenance schedule.

RESPONSE: COMPLIANT

13.2.1.4 Site supervisors shall be notified when maintenance or repairs are to be undertaken in any food sector packaging manufacturing, handling, or storage area.

RESPONSE: COMPLIANT

13.2.1.5 The maintenance supervisor and the site supervisor shall be informed if any repairs or maintenance pose a potential threat to food safety from foreign objects or contaminants (e.g., pieces of electrical wire, damaged light fittings, and loose overhead fittings). When possible, maintenance is to be conducted outside manufacturing times.

RESPONSE: COMPLIANT

13.2.1.6 Temporary repairs, where required, shall not pose a food safety risk and shall be included in routine inspections (refer to 2.5.4.3) and in the cleaning program. There shall be a plan in place to address completion of temporary repairs to ensure they do not become permanent solutions.

RESPONSE: COMPLIANT

13.2.1.7 Equipment located over raw or packaging materials, food sector packaging, or product conveyors shall be lubricated with food grade lubricants and their use controlled to minimize the contamination of the product. Machinery lubricant controls shall be in place to prevent contamination of food sector packaging from gear box oils, bearing lubricants, hydraulics, or any other source.

RESPONSE: COMPLIANT

13.2.1.8 Paint used in food sector packaging manufacturing, handling, and storage areas and product contact zones shall be suitable for use, intact, and free of chips and shall not be used on any food contact surfaces.

RESPONSE: COMPLIANT

13.2.2 Maintenance Staff and Contractors

Maintenance employees were observed following plant GMP requirements. Contractors and employees are trained on GMP's. Contractors are escorted at all times. If work is required to be completed on a piece of equipment the work is performed. Tools and parts are accounted for. Sanitation is documented on the Line Clearance Sheet.

13.2.2.1 Maintenance staff and contractors shall comply with the site's personnel hygiene requirements (refer to 13.3.4).

RESPONSE: COMPLIANT

13.2.2.2 All maintenance and other engineering contractors required to work on-site shall be trained in the site's food safety and hygiene procedures or shall be escorted at all times until their work is completed.

RESPONSE: COMPLIANT

13.2.2.3 Maintenance staff and contractors shall remove all tools, parts, and debris from areas where maintenance and repairs were conducted once it has been completed. They shall inform the appropriate supervisor so that hygiene and sanitation actions and a pre-operational inspection can be conducted prior to the restarting of operations.

RESPONSE: COMPLIANT

13.2.3 Calibration

A Calibration Work instruction is in place. The Work instruction was updated on Jul. 21, 2021. Equipment is calibrated against NIST standards or equipment specific standards. Calibrations are performed per regulatory and equipment requirements. The policy includes what to do with product should calibrated equipment be found to be out of calibration. Calibrated testing equipment is protected from unauthorized adjustments and damage. A register of equipment that requires calibration is maintained and was current. Metal Detectors were calibrated on May 17, 2021, X-rays were calibrated on May 17 and 19, 2021. Scales and checkweighers were calibrated on Dec. 29 thru Jan. 5, 2022.

13.2.3.1 The methods and responsibility for calibration and re-calibration of measuring, testing, and inspection equipment used for monitoring activities outlined in prerequisite programs, food safety plans and other process controls, or to demonstrate compliance with customer specifications shall be documented and implemented. Software used for such activities shall be validated as appropriate.

RESPONSE: COMPLIANT

13.2.3.2 Procedures shall be documented and implemented to address the resolution of potentially affected food sector packaging should measuring, testing, and inspection equipment be found to be out of calibration state.

RESPONSE: COMPLIANT

13.2.3.3 Calibrated measuring, testing, and inspection equipment shall be protected from damage and unauthorized adjustment.

RESPONSE: COMPLIANT

13.2.3.4 Equipment shall be calibrated against national or international reference standards and methods or to an accuracy appropriate to its use. In cases where standards are not available, the site shall provide evidence to support the calibration reference method applied.

RESPONSE: COMPLIANT

13.2.3.5 Calibration shall be performed according to regulatory requirements and/or to the equipment manufacturers' recommended schedule.

RESPONSE: COMPLIANT

13.2.3.6 A directory of measuring, testing, and inspection equipment requiring calibration and records of calibration tests shall be maintained.

RESPONSE: COMPLIANT

13.2.4 Pest Prevention

A Pest Control Program is in place. The program includes the methods used for pest prevention and methods for eliminating pests when required. The PCO reports to quality with findings. The interior devices are checked weekly on the interior and monthly on exterior of the facilities. Device maps were in place. The maps were updated on Jan 25, 2022. A list of approved chemicals is in place. The list was updated Jan 31, 2022. The chemicals were approved by the EPA. Only approved chemicals were used in the facility. SDS sheets were maintained electronically. Records of chemical applications were maintained. Only approved chemicals were used. Chemicals were applied by a licensed PCO. The PCO is licensed by the IDPH. The license expires on Dec. 31, 2023. Records for pest control were reviewed for Sept thru Jan. 2022. The records included the chemicals used and issues identified. If pest activity occurs in the plant, the area is treated. Any affected products or ingredients are disposed off and the disposal will be documented. Pesticides were not stored at the sites. No animals were allowed in the facilities.

13.2.4.1 A documented pest prevention program shall be effectively implemented. It shall: i. Describe the methods and responsibility for the development, implementation, and maintenance of the pest prevention program; ii. Record pest sightings and trend the frequency of pest activity to target pesticide applications; iii. Outline the methods used to prevent pest problems; iv. Outline the pest elimination methods and the appropriate documentation for each inspection; v. Outline the frequency with which pest status is to be checked; vi. Include on a site map the identification, location, number, and type of applied pest control/ monitoring devices; vii. List the chemicals used. The chemicals are required to be approved by the relevant authority and their Safety Data Sheets (SDS) made available; viii. Outline the methods used to make staff aware of the bait control program and the measures to take when they come into contact with a bait station; ix. Outline the requirements for staff awareness and training in the use of pest and vermin control chemicals and baits; and x. Measure the effectiveness of the program to verify the elimination of applicable pests and identify trends.

RESPONSE: COMPLIANT

13.2.4.2 Pest contractors and/or internal pest controllers shall: i. Be licensed and approved by the local relevant authority; ii. Use only trained and qualified operators who comply with regulatory requirements; iii. Use only approved chemicals; iv. Provide a pest prevention plan (refer to 2.3.2.7) that includes a site map indicating the location of bait stations, traps, and other applicable pest control monitoring devices; v. Report to a responsible authorized person on entering the premises and after the completion of inspections or treatments; vi. Provide regular inspections for pest activity with appropriate action taken if pests are present; and vii. Provide a written report of their findings and the inspections and treatments applied.

RESPONSE: COMPLIANT

13.2.4.3 Pest activity risks shall be analyzed and recorded. Inspections for pest activity shall be undertaken on a regular basis by trained site personnel and the appropriate action taken if pests are present. Identified pest activity shall not present a risk of contamination to raw materials or food sector packaging. Records of all pest control inspections and applications shall be maintained.

RESPONSE: COMPLIANT

13.2.4.4 Raw materials or packaging, processing aids, work-in-progress, or food sector packaging that is found to be contaminated by pest activity shall be effectively disposed of and the source of pest infestation investigated and resolved.

RESPONSE: COMPLIANT

13.2.4.5 Pesticides shall be clearly labeled and stored per 13.6.2 if kept on-site.

RESPONSE: COMPLIANT

13.2.4.6 No animals shall be permitted on-site in food sector packaging manufacturing, handling, or storage areas.

RESPONSE: COMPLIANT

13.2.5 Cleaning and Sanitation

Methods are in place for the cleaning of the production areas. Tools for cleaning are in place and are marked and stored away from the production line. Equipment that is not in used is covered. Pre-operational inspections are conducted by QA after sanitation has been performed. Employee amenities are checked during the monthly GMP audit. Verification of sanitation is with ATP swabbing. An inventory of cleaning chemicals is maintained. The chemicals are safe to use in a food facility. The technical data sheets were reviewed. SDS sheets are in place for all chemicals. The chemicals are stored in locked cabinets. Empty chemical containers are triple rinsed and recycled. Records for sanitation were reviewed for Jun. thru Dec. 2021 and were complete. Line clearance checks were reviewed for Jan. 2022. The records were complete.

13.2.5.1 The methods and responsibility for the effective cleaning of food sector packaging manufacturing, handling and storage areas, and staff amenities shall be documented and implemented.

RESPONSE: COMPLIANT

13.2.5.2 Cleaning equipment, tools, racks, and other items used in support of the cleaning and sanitizing program shall be clearly identified, stored, and maintained in a manner that prevents contamination of food sector packaging manufacturing, handling, and storage areas and equipment.

RESPONSE: COMPLIANT

13.2.5.3 Adjacent production equipment shall be covered or shut down and raw and packaging materials, work-in-progress, and food sector packaging shall be moved from the vicinity if using compressed air hoses to clean.

RESPONSE: COMPLIANT

13.2.5.4 Pre-operational inspections shall be conducted following cleaning and sanitation operations to ensure manufacturing areas, product contact surfaces, equipment, staff amenities, and other essential areas are clean before the start of production. Inspections shall be conducted by qualified personnel to ensure the areas are cleaned at a defined frequency.

RESPONSE: COMPLIANT

13.2.5.5 The responsibility and methods used to verify the effectiveness of the cleaning procedures shall be documented and implemented. A verification schedule shall be prepared. A record of pre-operational hygiene inspections, cleaning and sanitation activities, and verification activities shall be maintained.

RESPONSE: COMPLIANT

13.2.5.6 Appropriate cleaning agents shall be purchased in accordance with applicable legislation and suitable for use. The site shall ensure that only trained staff handle cleaning agents and that it is according to manufacturer instructions. Documentation, storage, usage, and disposal of cleaning agents shall comply with 13.6.2.

RESPONSE: COMPLIANT

13.3.1 Personnel Welfare

Employees with an obvious illness are not allowed into the processing areas. There were no employees observed with an obvious illness. Temperatures are monitored upon entering the facility. Employees are trained on what to do when there is a bodily fluid spill. Sanitation and housekeeping along with the supervisors, are trained on how to handle bodily fluid spills. Spill kits are in place. There were no employees observed with open cuts or sores. Metal detectable band aids were used.

13.3.1.1 Personnel who are known to be carriers of infectious diseases that present a health risk to others on-site shall not engage in the manufacture of food sector packaging or enter areas where food sector packaging is exposed. Code Amendment #1 A medical screening procedure shall be in place for all employees, visitors and contractors who handle exposed product or food contact surfaces.

RESPONSE: COMPLIANT

13.3.1.2 The site shall have measures in place to prevent contact of raw and packaging materials, work-in-progress, food sector packaging, and product contact surfaces from any bodily fluids, open wounds, coughing, sneezing, spitting, or any other means. In the event of an injury that causes spillage of bodily fluid, a properly trained employee shall ensure that all affected areas have been adequately cleaned and that all affected materials have been quarantined and/or disposed of.

RESPONSE: COMPLIANT

13.3.1.3 Personnel with exposed cuts, sores, or lesions shall not engage in handling raw and packaging materials, work-in-progress, food sector packaging, and product contact surfaces. Minor cuts or abrasions on exposed parts of the body shall be covered with a colored bandage containing a metal-detectable strip or an alternative suitable waterproof and colored dressing.

RESPONSE: COMPLIANT

13.3.2 Handwashing

Employees were observed washing hands when entering the processing areas. Sinks are located at the entrances to the processing areas. The sinks are hands free, have warm water, liquid soap, and a garbage can. Signage is posted instruction employees to wash hands. The signage is in English and Spanish. Hands were washed before putting on gloves.

13.3.2.1 Personnel shall have clean hands, and hands shall be washed by all personnel, including staff, contractors, and visitors: i. On entering production areas; ii. After each visit to a toilet; iii. After using a handkerchief; iv. After smoking, eating, or drinking; and v. After handling waste or chemicals.

RESPONSE: COMPLIANT

13.3.2.2 Handwash stations shall be provided in appropriate areas that support the capability of site personnel and visitors to wash their hands as outlined in 13.3.2.3.

RESPONSE: COMPLIANT

13.3.2.3 Handwash stations shall have: i. Basins constructed of stainless steel or similar non-corrosive material; ii. A potable water supply at an appropriate temperature; iii. Liquid hand soap within a fixed dispenser; iv. Paper towels or effective hand dryer; and v. A means of containing used paper towels.

RESPONSE: COMPLIANT

13.3.2.4 Signage in appropriate languages instructing people to wash their hands before entering the food sector packaging manufacturing, handling, and storage areas shall be provided in a prominent position in break rooms, at break rooms exits, toilet rooms, and in outside eating areas if applicable.

RESPONSE: COMPLIANT

13.3.2.5 When gloves are used, personnel shall maintain the handwashing practices outlined above.

RESPONSE: COMPLIANT

13.3.3 Clothing and Personal Effects

A risk analysis was conducted on Dec. 18, 2019, on clothing and the hair policy. The risk analysis showed that the clothing and hair policy did not pose a threat to products. The risk assessment was reviewed during the annual review with no changes. Smocks worn by employees are stored in separate areas. Clothing and shoes were clean at the start of the shift. Extra smocks are available should they become soiled. Disposable gloves were observed being changed after breaks. Protective clothing was manufactured from appropriate materials. Racks were provided for protective clothing. There were no employees observed wearing jewelry or loose objects above the waist.

13.3.3.1 The site shall have a clothing and hair policy that protects raw and packaging materials, work-in-progress, food sector packaging, and product contact surfaces from unintentional contamination.

RESPONSE: COMPLIANT

13.3.3.2 Clothing worn by staff engaged in handling food sector packaging shall be maintained, stored, laundered, and worn so as not to present a contamination risk to products.

RESPONSE: COMPLIANT

13.3.3.3 Clothing worn by staff engaged in manufacturing and warehouse processes shall be made from materials that will not contaminate raw and packaging materials, workin-progress, and food sector packaging. Clothing and shoes shall be clean at the commencement of each shift, maintained in a serviceable condition, and changed where they present a product contamination risk.

RESPONSE: COMPLIANT

13.3.3.4 When protective clothing (e.g. frocks, smocks, aprons, boots, gloves, face shields, etc.) is used, hooks racks, cabinets, or other forms of off the floor storage shall be provided for temporary storage when staff leave the manufacturing area and shall be provided in close proximity or adjacent to the personnel access doors and handwashing stations. All clothing stored on-site shall be maintained and stored so as not to present a contamination risk to raw or packaging materials, work-in-progress, and food sector packaging.

RESPONSE: COMPLIANT

13.3.3.5 Gloves used when handling food sector packaging material shall be clean and replaced when needed.

RESPONSE: COMPLIANT

13.3.3.6 Jewelry and other loose objects shall not be worn or taken into any area where raw and packaging materials, work-in-progress, or food sector packaging is exposed. Wearing plain bands with no stones and medical alert bracelets that cannot be removed can be permitted; however, the site will need to consider their customer requirements and the applicable food legislation.

RESPONSE: COMPLIANT

13.3.3.7 All exceptions shall meet regulatory and customer requirements and shall be subject to a risk assessment and evidence of ongoing risk management.

RESPONSE: COMPLIANT

13.3.4 Visitors

Visitors are trained on the GMP's prior to entering the processing areas. Visitors and management were observed wearing proper clothing. Everyone is required to remove jewelry and loose objects above the waist. Anyone with an obvious illness is not allowed into the facilities. Everyone must enter and exit through the proper doorways. Visitors are trained in the GMP's prior to entering the processing areas.

13.3.4.1 All visitors shall be trained in, and comply with, applicable food safety and hygiene procedures before entering food sector packaging manufacturing, handling, or storage areas. Visitors shall be trained in, and comply with, additional food safety policies, such as maintenance and cleaning procedures, as appropriate to the purpose of the visit. Where applicable, policies shall define exceptions for visitors when they are escorted at all times.

RESPONSE: COMPLIANT

13.3.4.2 All visitors shall wear suitable clothing and footwear when entering any food sector packaging manufacturing, handling, or storage areas.

RESPONSE: COMPLIANT

13.3.4.3 Visitors shall enter and exit food sector packaging manufacturing, handling, and storage areas through the designated entrance points.

RESPONSE: COMPLIANT

13.3.4.4 Visitors exhibiting visible signs of illness shall be prevented from entering areas in which food sector packaging is handled or processed.

RESPONSE: COMPLIANT

13.3.5 Staff Amenities (change rooms, toilets, break rooms)

Employee amenities are on a daily sanitation schedule. Change rooms are not provided. An area is provided for employees to put on smocks prior to entering the processing areas. Restrooms are provided for employees. The restrooms are located away from the processing areas. The areas were clean. Sanitary drainage is connected directed to the sewage system. Procedures are in place on how to handle drain backups. Sinks are provided in the restroom. The sinks are designed as outlined in 13.3.2.3. A drain back up procedure is in place. The lunch room is located away from the production areas. The lunch room was clean, well lighted, had a sink, refrigeration and microwaves. Outside eating areas were clean. Garbage cans were provided.

13.3.5.1 Staff amenities shall have documented cleaning procedures, be supplied with appropriate lighting and ventilation, and shall be made available for the use of all persons engaged in the handling and storage of food sector packaging.

RESPONSE: COMPLIANT

13.3.5.2 Where applicable, facilities shall be provided to enable staff to change into and out of protective clothing as required. Provision shall be made for staff to store their street clothing and personal items separate from food sector packaging manufacturing, handling, or storage areas.

RESPONSE: NOT APPLICABLE

EVIDENCE: Change rooms are not provided.

13.3.5.3 Toilet rooms shall be: i. Designed and constructed so that they are separate from any food sector packaging manufacturing, handling, or storage areas; ii. Accessed from operations via an airlock vented to the exterior or through an adjoining room; iii. Sufficient in number for the maximum number of staff; iv. Constructed so that they can be easily cleaned and maintained; v. Include an area inside or nearby for storing protective clothing, outer garments, and other items while using the facilities; and vi. Kept clean and tidy. Tools/equipment used for cleaning toilet rooms shall not be used to clean food sector packaging manufacturing areas.

RESPONSE: COMPLIANT

13.3.5.4 Sanitary drainage shall not be connected to any other drains within the premises and shall be directed to a septic tank or a sewerage system in accordance with regulations.

RESPONSE: COMPLIANT

13.3.5.5 A procedure shall document how to minimize the potential for contamination to the premises, personnel, raw and packaging materials, work-in-progress, and food sector packaging in the event of a sewage backup.

RESPONSE: COMPLIANT

13.3.5.6 Handwash stations shall be provided immediately outside or inside the toilet room and designed as outlined in 13.3.2.3.

RESPONSE: COMPLIANT

13.3.5.7 Separate break room facilities shall be provided away from food sector packaging manufacturing, handling, or storage areas. Break rooms shall be kept clean and tidy and free from waste materials and pests.

RESPONSE: COMPLIANT

13.3.5.8 Where outside eating areas are provided, they should be kept clean and free from waste materials and maintained in a manner that minimizes the potential for introduction of contamination including pests to the site.

RESPONSE: COMPLIANT

13.4.1 Staff Engaged in Food Handling and Processing Operations

Employees were observed entering through the proper doorways. GMP's were followed. Packaging materials were stored off of the floor. There was no evidence of eating or drinking in the processing or storage area. Waste containers were color coded. No cross contamination was observed. The flow of employees was controlled.

13.4.1.1 All personnel engaged in food sector packaging manufacture, handling, and storage operations shall comply with the following practices: i. Personnel entry to production areas shall be through designated access doors only; ii. All doors are to be kept closed. Doors shall not be left open for extended periods when access is required for waste removal or receiving of product/ingredient/packaging; iii. Raw and packaging materials, work-in-progress, and food sector packaging shall be maintained appropriately, kept off the floor when applicable, and handled and stored in a manner to prevent damage and contamination; and iv. Waste shall be contained in the bins identified for this purpose and removed from the manufacturing area on a regular basis and not left to accumulate.

RESPONSE: COMPLIANT

13.4.1.2 Personnel working in or visiting food sector packaging manufacturing, handling, or storage operations shall ensure that: i. Eating, drinking, smoking, or spitting is not permitted in areas where food sector packaging is manufactured, handled, stored, or exposed. ii. Drinking water is permitted in food sector packaging manufacturing, handling, and storage areas in a method that will not cause a food safety risk to raw and packaging materials, workin-progress, food sector packaging, and equipment.

RESPONSE: COMPLIANT

13.4.1.3 The manufacturing process shall be controlled such that food sector packaging is safe and free from contamination. Procedures shall be in place to prevent cross-contamination of food sector packaging from contaminated materials, cleaning agents, or chemicals.

RESPONSE: COMPLIANT

13.4.1.4 The flow of personnel in food sector packaging manufacturing, storage, and handling areas shall be managed such that the potential for contamination is minimized.

RESPONSE: COMPLIANT

13.5.1 Water Supply

Only potable water was used in the facilities. There was an adequate amount of water available for cleaning. The sites use a minimal amount of water for sanitation. Backflow prevention is in place. The backflows were last tested in Mar. 21, 2021. Non-potable water was not used . Water was not stored at the plants.

13.5.1.1 Adequate supplies of hot and cold clean water shall be provided for use during manufacturing operations as needed and to enable effective cleaning of the premises and equipment.

RESPONSE: COMPLIANT

13.5.1.2 The delivery of water within the premises shall ensure potable water is not contaminated. Testing of the backflow system, where possible, shall be conducted at least annually and records shall be maintained.

RESPONSE: COMPLIANT

13.5.1.3 The use of non-potable water shall be controlled such that: i. There is no cross-contamination between potable and non-potable water lines; ii. Non-potable water piping and outlets are clearly identified; and iii. Hoses, taps, and other similar sources of possible contamination are designed to prevent back flow or back siphonage.

RESPONSE: NOT APPLICABLE

EVIDENCE: Non-potable water was not used.

13.5.1.4 Where water is stored on-site, storage facilities shall be adequately designed, constructed, and maintained to prevent contamination.

RESPONSE: NOT APPLICABLE

EVIDENCE: Water was not stored on site.

13.5.2 Water Quality

The water reports reviewed for Elk Grove Village, Bensenville, and Bartlett for 2021, showed that the water used met national quality requirements. Water was tested at all three sites on between May 7 and 15, 2021. The results for Coliform were <1.1 MNP/100 ml. using test method SMEWW 22nd Ed. 9221E.

13.5.2.1 Water shall comply with local, national, or internationally recognized potable water microbiological and quality standards as required when used for: i. Handwashing; ii. As a raw material or processing aid; iii. Cleaning of product contact surfaces and equipment; or iv. The manufacture of steam that will come into contact with food sector packaging or used to heat water that will come into contact with food sector packaging.

RESPONSE: COMPLIANT

13.5.2.2 Microbiological analysis of the water supply shall be conducted to verify the cleanliness of the supply, the monitoring activities, and the effectiveness of the treatment measures implemented. Samples for analysis shall be taken on-site at sources supplying water for the process, handwashing, and/or cleaning, or from within the site. The frequency of analysis shall be risk-based and at a minimum annually.

RESPONSE: COMPLIANT

13.5.2.3 Water shall be analyzed using reference standards and methods.

RESPONSE: COMPLIANT

13.5.3 Air and Other Gases

Compressed air is filtered with .01 mm micron filters. The filters are on a schedule. Compressed air is tested monthly for APC. Results for Jan. 2022 were in specification.

13.5.3.1 Dry ice, compressed air, and other gasses (e.g., nitrogen, carbon dioxide) that contact food sector packaging or product contact surfaces shall be food-grade, clean, and present no risk to food safety.

RESPONSE: COMPLIANT

13.5.3.2 Compressed air and other systems used to store or dispense gases that come into contact with food sector packaging or product contact surfaces shall be maintained and regularly monitored for quality and potential food safety hazards. The frequency of analysis shall be risk-based and at a minimum annually.

RESPONSE: COMPLIANT

13.6.1 Storage of Materials and Product

How ingredients and packaging materials are to be stored is documented in SyteLine. When an ingredient is received the program tells the employee where it is to be stored. Stock rotation is based on First Expired First Out. No expired products or ingredients were observed in the facility. Equipment storage areas were clean. Alternative storage was not used. Storage areas were well maintained and clean. The molds are stored in a specified area and were covered.

13.6.1.1 The site shall document and implement a storage plan that allows for the safe, hygienic storage of raw and packaging materials, work-in-progress, food sector packaging, finished product returns, production equipment, processing aids, and chemicals that impact food safety.

RESPONSE: COMPLIANT

13.6.1.2 The responsibility and methods for ensuring effective stock rotation principles are applied shall be documented and implemented to ensure that all raw materials, work-in-progress, rework, and food sector packaging are utilized within their designated shelf life, where applicable.

RESPONSE: COMPLIANT

13.6.1.3 Equipment storage rooms shall be designed and constructed to allow equipment to be stored in a hygienic manner.

RESPONSE: COMPLIANT

13.6.1.4 Where raw and packaging materials, work-in-progress, and food sector packaging are held under temporary or overflow conditions that are not designed for the safe storage of those goods, a risk analysis shall be performed to ensure the integrity of those goods is maintained, they are not at risk of contamination, and there are no other food safety concerns.

RESPONSE: NOT APPLICABLE

EVIDENCE: Alternative storage was not used.

13.6.1.5 Rooms and equipment used for the storage of raw and packaging materials, work-in-progress, and food sector packaging shall be constructed to protect the product from contamination and deterioration.

RESPONSE: COMPLIANT

13.6.1.6 Where required, procedures shall be in place for effective storage of printing plates, cylinders, and print blankets.

RESPONSE: COMPLIANT

13.6.2 Storage and Use of Hazardous Chemicals and Toxic Substances

Chemicals and solvents were stored in locked cabinets in the production area. SDS sheets were in place. All chemicals were labeled. The chemicals were used per manufacturer requirements. Employees are trained in chemical handling and are provided with protective equipment when required. Obsolete chemicals are removed by a third party. Empty chemicals containers are triple rinsed and recycled. Spill kits were available for spills.

13.6.2.1 Hazardous chemicals and toxic substances, including solvents and agents with the potential for contamination of food sector packaging, shall be: i. Clearly labelled, identifying and matching the contents with their containers; ii. Included in a current list of all chemicals and toxic substances that are stored on-site; and iii. Supplemented with a current Safety Data Sheet (SDS) that is made available to all staff.

RESPONSE: COMPLIANT

13.6.2.2 Storage of hazardous chemicals and toxic substances shall be: i. Located in an area with appropriate signage indicating that the area is for hazardous storage; ii. Controlled, lockable, and accessible only by personnel trained in the storage and use of chemicals; iii. Adequately ventilated; iv. Stored where intended and not comingled (e.g., food versus non-food grade); v. Designed such that there is no cross-contamination between chemicals; and vi. Stored in a manner that prevents hazards to raw and packaging materials, work-in-progress, food sector packaging, and product contact surfaces.

RESPONSE: COMPLIANT

13.6.2.3 Hazardous chemicals and toxic substances shall be correctly labeled and: i. Used only according to manufacturers' instructions; ii. Controlled to prevent contamination or a hazard to raw and packaging material, work-in-progress, food sector packaging, or finished product contact surfaces; iii. Returned to the appropriate storage areas after use; and iv. Be compliant with national and local legislation.

RESPONSE: COMPLIANT

13.6.2.4 Employees who handle hazardous chemicals and toxic substances, including pesticides and cleaning chemicals, shall: i. Be properly trained on handling and usage; ii. Be provided with first aid equipment and personnel protective equipment; and iii. Ensure compliance to the proper identification, storage, usage, disposal, and clean-up requirements as defined.

RESPONSE: COMPLIANT

13.6.2.5 The site shall dispose of obsolete inventory and empty containers of chemicals, pesticides, and toxic substances in accordance with site and regulatory requirements and ensure that: i. Single-use containers are not reused; ii. Containers are segregated and securely stored prior to collection; and iii. Containers are disposed through an appropriate vendor.

RESPONSE: COMPLIANT

13.6.2.6 In the event of a hazardous chemical or toxic substance spill, the site shall: i. Have spillage clean-up instructions to ensure that the spill is properly contained; and ii. Be equipped with spillage kits and cleaning equipment.

RESPONSE: COMPLIANT

13.6.3 Loading, Transport, and Unloading Practices

Receiving and Shipping Instructions are in place. The instructions were up dated on May 21, 2019. Shipping and receiving is conducted at different doors. The packaging is used internally and not shipped to other sites. Trailers will be inspected if product is to be shipped and sealed after loading.

13.6.3.1 The practices applied during transport, loading, and unloading of raw and packaging materials and food sector packaging shall be documented and implemented. Practices shall be conducted to prevent cross-contamination, maintain appropriate storage conditions, and ensure product integrity.

RESPONSE: COMPLIANT

13.6.3.2 Vehicles (e.g., semi-trucks, trailers, vans, containers) used for transporting food sector packaging shall be inspected prior to loading to ensure they are clean, in good repair, suitable for the purpose, and free from odors or other conditions that may impact negatively on the food sector packaging.

RESPONSE: COMPLIANT

13.6.3.3 Vehicles (e.g. semi-trucks, trailers, vans, containers) used for transporting food sector packaging from the site shall be secured from tampering using a seal or other acceptable device or system as agreed upon by the carrier and customer.

RESPONSE: COMPLIANT

13.7.1 Control of Foreign Matter Contamination

A Foreign Material policy is in place. The policy was updated on Jul. 7, 2021. All employees are responsible for foreign material control. Monthly and daily inspections are conducted to ensure the plants and equipment remain in good condition. There were no glass or ceramic items in the processing areas. Glass and brittle plastic registers are in place for all plants. The registers were updated on Nov. 2021. The registers were complete for the items reviewed during the audit. Daily and monthly inspections are conducted of the processing areas. There are no glass instruments and MIG thermometers in the processing areas. Wooden pallets were in good condition. There were no loose metal objects on or over equipment. Knives are controlled and were clean.

13.7.1.1 The responsibility and methods used to prevent foreign matter contamination of raw and packaging materials, work-in-progress, food sector packaging, and product contact surfaces shall be documented, implemented, and communicated to all staff.

RESPONSE: COMPLIANT

13.7.1.2 Inspections shall be performed to ensure that the site and equipment remain in good condition and equipment has not become detached or deteriorated and is free from potential contaminants.

RESPONSE: COMPLIANT

13.7.1.3 Containers, storage and transport vessels, equipment, utensils, and tools made of glass, porcelain, ceramics, and brittle plastics shall not be permitted in food sector packaging manufacturing, handling, and storage areas. Exceptions shall include product made from, or packaged in these materials, measurement instruments with glass dial covers or MIG thermometers required under regulation or part of the processing equipment, and other essential items shielded with shatterproof coverings.

RESPONSE: COMPLIANT

13.7.1.4 Glass, porcelain, ceramics, and brittle plastics that are permitted in manufacturing areas shall be listed on a glass inventory and inspected at a frequency based on risk to confirm that they have not been damaged or to monitor for further damage prior to repair or replacement. Regular inspections of product handling/contact zones shall be conducted (refer to 2.5.4.3) to ensure they are free of glass or similar material and to establish changes to the condition of objects listed in the glass inventory.

RESPONSE: COMPLIANT

13.7.1.5 Wooden pallets and other wooden objects used in food sector packaging manufacturing, handling, and storage areas shall be dedicated for that purpose, clean, and maintained in good order. Their condition shall be subject to regular inspection.

RESPONSE: COMPLIANT

13.7.1.6 Wooden pallets, wooden top frames, and wooden utensils used in food sector packaging, manufacturing, handling, and storage areas shall be dedicated for that purpose, clean, maintained in good order, and subject to regular inspection.

RESPONSE: COMPLIANT

13.7.1.7 Loose, deteriorated, or damaged objects on and above structures and equipment in food sector packaging manufacturing, handling, and storage areas shall be controlled, repaired, or replaced to prevent foreign object contamination and other food safety hazards affecting raw and packaging materials, work-in-progress, and food sector packaging.

RESPONSE: COMPLIANT

13.7.1.8 Knives and cutting tools used in manufacturing operations shall be controlled, kept clean, and well maintained so as not to present a hazard to raw materials, work-in progress, or food sector packaging. Snap-off blades shall not be used in food sector packaging manufacturing, handling, or storage areas.

RESPONSE: COMPLIANT

13.7.2 Managing Foreign Matter Contamination Incidents

In case of glass or brittle plastic breakage, the area is isolated, cleaned, and inspected. Cleaning tools are disposed off and shoes are inspected. Any affected product is disposed off.

13.7.2.1 In circumstances where glass or similar brittle material breakage occurs, the affected area and equipment shall be isolated, cleaned, and thoroughly inspected prior to restarting operations. Utensils and equipment used for clean-up and footwear of those walking in the vicinity shall be inspected and cleaned if necessary.

RESPONSE: COMPLIANT

13.8.1 Waste Disposal

A Waste Management policy is in place. The policy was updated on Apr. 5, 2019. Waste was contained in bins and stored in designated areas. Waste disposal bins were in good condition and color coded. The waste collection area was clean. Reviews of waste management is conducted during each shift by QA.

13.8.1.1 The responsibility and methods used to collect, handle, and store waste prior to removal from the premises shall be documented and implemented. This shall include consideration of the path of waste removal to prevent cross contamination in food sector packaging manufacturing, handling, and storage areas. Disposal of hazardous chemicals and toxic substances shall comply with 13.6.2.5.

RESPONSE: COMPLIANT

13.8.1.2 Waste shall be contained in bins identified for its purpose, located in designated areas, and removed at a routine frequency that avoids build-up in food sector packaging, manufacturing, handling, and storage areas.

RESPONSE: COMPLIANT

13.8.1.3 Waste disposal equipment, trolleys, vehicles, and collection bins shall be maintained in a serviceable condition and cleaned regularly so as not to attract pests and other vermin. Designated waste accumulation and storage areas shall be well-maintained while awaiting external collection.

RESPONSE: COMPLIANT

13.8.1.4 Reviews of the effectiveness of waste management shall form part of regular site inspections (refer to 2.5.4.3), and the results of the inspections shall be included in the relevant inspection reports.

RESPONSE: COMPLIANT

13.8.1.5 Where applicable, a documented procedure shall be in place for the controlled disposal of trademarked or printed packaging materials and finished products. Where a contracted disposal service is used, the disposal process shall be reviewed regularly to confirm compliance.

RESPONSE: COMPLIANT